Americas Healthcare: Biotechnology: Takeaways from the ASCO abstracts

Salveen Richter, CFA
+1(212)934-4204 |
salveen.richter@gs.com
Goldman Sachs & Co. LLC

Corinne Johnson
+1(917)343-1445 |
corinne.johnson@gs.com
Goldman Sachs & Co. LLC

Mark Aleynick, Ph.D.
+1(212)357-6820 |
mark.aleynick@gs.com
Goldman Sachs & Co. LLC

Matt Dellatorre, Ph.D.
+1(212)855-0830 |
matt.dellatorre@gs.com
Goldman Sachs & Co. LLC

Elizabeth Webster, Ph.D.
+1(212)357-9925 |
elizabeth.webster@gs.com
Goldman Sachs & Co. LLC

Tommie Reerink, CFA
+1(212)357-2470 |
tommie.reerink@gs.com
Goldman Sachs & Co. LLC

Kevin Strang, Ph.D.
+1(212)357-7227 |
kevin.strang@gs.com
Goldman Sachs & Co. LLC

Shrunatra Mishra
+1(332)245-7673 |
shrunatra.mishra@gs.com
Goldman Sachs India SPL

Erik Wong
+1(212)357-9964 | erik.wong@gs.com
Goldman Sachs & Co. LLC

Lydia Erdman
+1(212)357-6383 |
lydia.erdman@gs.com
Goldman Sachs & Co. LLC

We will attend the American Society of Clinical Oncology (ASCO) annual meeting (May 29-June 2), ahead of which regular abstracts were released. Within, we provide our views on key presentations within our coverage, notably: (1) full Ph3 results from **IMNM**'s varegacestat in desmoid tumors, where key secondary endpoint data including 94.2%/88.9% 1-year/2-year progression-free survival (PFS) rates and a statistically significant 2.42-point reduction in pain further supports a best-in-class position over Merck KGaA's Ogsiveo; (2) updated Ph1 data for **GILD**'s TUB-040 continue to show encouraging results, in-line with the prior update at ESMO, and support a potentially differentiated profile in ovarian cancer; (3) maintenance and PK data for **SDNX**'s Revuforj that support a potential launch tailwind (in KMT2Ar AML) and superior competitive positioning (in NPM1m AML); (4) detailed 5-year Ph2 data from **MRNA/MRK**'s individualized neoantigen therapy in adjuvant melanoma (post the prior top-line release), where we are encouraged by the improved trend in OS and await Ph3 data likely this year. We also look to late-breakers (see our conference planner here) from: **SMMT**/Akeso (overall survival data from the Ph3 HARMONi-6 (China-only) study of PD-1xVEGF-bispecific ivonescimab and chemotherapy in 1L squamous non-small cell lung cancer (NSCLC) will be shared in the plenary session, which typically bodes well, representing the first Ph3 ivo-chemo-combination OS data in frontline lung, with readthrough to SMMT's global Ph3 HARMONi-3 trial and potential implications for the broader oncology landscape), **IDYA** (darovasertib in metastatic uveal melanoma (mUM) following positive topline data last month), **INCY** (Ph3 results for tafasitamab in 1L DLBCL), and **RLAY** (competitor CELC data in HR+/HER2- breast cancer, where our KOL feedback suggests ~12-month PFS as the minimum and ~14-15+ months to drive uptake given gedatolisib's IV administration).

Company highlights

Summit Therapeutics (SMMT, Buy)
Ivonescimab plus chemotherapy versus tislelizumab plus chemotherapy in previously untreated advanced squamous non–small cell lung cancer: overall survival results of the phase 3 harmoni-6 trial

SMMT's partner Akeso will share overall survival (OS) data from the single-region (China) Ph3 HARMONi-6 study of ivonescimab (ivo; a PD-1xVEGF bispecific) + chemotherapy vs. Tevimbra (ONC's anti-PD-1, similar to MRK's Keytruda) +

chemotherapy in frontline squamous non-small cell lung cancer (NSCLC). The abstract is embargoed until 8AM ET on May 31 given it was selected for presentation in the Plenary Session, which typically bodes well.

We see laterals to SMMT from key competitor presentations at ASCO, most notably:

- **BNTX** (covered by Asad Haider), who will present Ph2 data from the global Ph2/3 ROSETTA Lung-02 of PDL1xVEGF pumitamig in 1L metastatic NSCLC, noting the abstract titled "Phase 2 data from ROSETTA Lung-02, a global randomized phase 2/3 trial of pumitamig (PD-L1 × VEGF-A bsAb) + chemotherapy in 1L NSCLC." Per the abstract, pumitamig demonstrated a 66.7% objective response rate (ORR) in patients with non-squamous NSCLC (n=21), and a 73.7% ORR in patients with squamous NSCLC (n=19). Median best change in tumor volume was -38.2% (non-squamous -36.6%; squamous -39.7%). Median treatment duration was 4.5 months. In the safety set (N=43), grade ≥3 treatment-related adverse events (TRAEs) were reported in 19 (44.2%) patients and were considered pumitamig-related in 8 (18.6%). Pumitamig-related TRAEs led to treatment discontinuation in 2 (4.7%) patients. Immune related AEs (irAEs) occurred in 6 (14.0%) patients, and grade ≥3 irAEs in 1 (2.3%). Bleeding events were reported in 7 (16.3%) patients, with only 1 event being grade 3. *We note the data is broadly in-line with SMMT's ivo in combination with chemotherapy, where recall, prior Ph2 ivo data demonstrated an ORR of 54.2%/71.4% in non-squamous/squamous patients, and is overall validating for the PD-1/L1xVEGF class. In the single region (China) Ph3 HARMONi-6 study in 1L squamous non-small cell lung cancer (NSCLC) patients, ivo + chemotherapy demonstrated an ORR of 76%, and an 11.1 month progression free survival (PFS) vs. 6.9 months for Tevimbra (Beigene's PD1 antibody, similar to MRK's Keytruda) + chemotherapy, with a PFS hazard ratio (HR) of 0.60 (p<0.0001). We look to SMMT/Akeso's plenary presentation on HARMONi-6 for clarity on OS benefit, noting prior Ph2 ivo data where Akeso provided the lower bound of 22.5 months for the OS confidence interval (OS was not mature at the time of analysis).*
- **PFE** (covered by Asad Haider), who will present Ph2 data for SSGJ-707 (PF-08634404) in 1L PD-L1+ (tumor proportion score (TPS) ≥1%) NSCLC, noting the abstract titled "Updated results from a phase 2 trial of SSGJ-707 (PF-08634404), a PD-1/VEGF bispecific antibody, as monotherapy in patients with advanced non-small cell lung cancer (NSCLC)." Per the abstract, in patients treated with the FDA-aligned dose of 10 mg/kg Q3W (n = 34) with a 15.2mo median duration of follow-up, confirmed ORR was 67.6%, median PFS was 12.4 months, and median OS was not reached. On safety, among all treated patients (n = 83), treatment-related adverse events (TRAEs) occurred in 92.8%; grade ≥3 TRAEs occurred in 42.2%. VEGF-related AEs occurred in 62.7% (grade ≥3, 18.1%) of patients, and immune-mediated AEs occurred in 37.3% (grade ≥3, 8.4%). *We note the data is broadly in-line with prior data from SMMT/Akeso's larger Ph3 HARMONi-2 study (n=398) investigating ivo as a monotherapy head-to-head against Keytruda in frontline PD-L1+ NSCLC, where recall, ivo demonstrated an ORR of 50%, and an 11.1mo PFS vs. 5.8mo for Keytruda (HR=0.51, p<0·0001), and is overall validating for the PD-1/L1xVEGF class.*
- **Kelun** (covered by Ziyi Chen) will present data from the single region (China) Ph3

OptiTROP-Lung05 study of TROP2 ADC sacituzumab tirumotecan (sac-TMT) in combination with Keytruda as 1L for PD-L1-positive (PD-L1 TPS≥ 1%) advanced NSCLC, noting the abstract titled "Sacituzumab tirumotecan (sac-TMT) plus pembrolizumab (P) versus pembrolizumab (P) as first-line treatment for PD-L1–positive advanced non-small cell lung cancer (NSCLC): Results from the randomized phase 3 OptiTROP-Lung05 study." Toplined as having positive data last November, the full data per the abstract (n=413, median follow-up of 10.5 months) shows that PFS was significantly longer in the sac-TMT combination group vs. Keytruda monotherapy (median, not reached vs 5.7 months; HR=0.35; 95% CI, 0.26-0.47; p< 0.0001). The data for OS were not mature, and a favorable trend was observed in the sac-TMT + P group (HR, 0.55; 95% CI, 0.36-0.85). ORR was 70.2% in the sac-TMT + P group versus 42.0% in the Keytruda group. In the pre-specified PDL1 subgroups, the HRs for PFS in patients with TPS 1-49% and TPS ≥ 50% were 0.28 (95% CI, 0.19-0.41) and 0.47 (95% CI, 0.29-0.77). In the pre-specified histology subgroups, the HRs for PFS in patients with non-squamous and squamous histologies were 0.28 (95% CI, 0.18-0.43) and 0.44 (95% CI, 0.29-0.66). Grade ≥ 3 TEAEs occured in 55.3% of patients in the sac-TMT combination group and 31.4% in the Keytruda monotherapy group. TEAEs led to discontinuation of sac-TMT/ pembrolizumab in 3.8%/5.3% of patients in the sac-TMT combination group, while discontinuation of Keytruda in the monotherapy group occurred in 4.9% of patients. *Kelun is partnered with MRK (covered by Asad Haider) for global sac-TMT development. Acknowledging the caveat that the single-region (China) OptiTROP-Lung05 study employed Keytruda monotherapy as the comparator (noting Keytruda+chemotherapy is considered the global standard of care), the magnitude of benefit and data overall appear impressive per the HRs presented to date, albeit we await more mature data for clarity on the absolute PFS and OS benefit.*

Ideaya Biosciences (IDYA, Neutral)

IDYA will present detailed data from their Ph2/3 darovasertib plus crizotinib data in metastatic uveal melanoma (mUM), which met positive expectations last month on median progression-free survival (mPFS) with their toplined data (slides), in a late breaker oral presentation on June 1st, 2026 (abstract embargoed until the morning of the presentation). Recall, topline data showed an impressive 6.9 months mPFS 1L HLA-A2(-) mUM patients (n=210), versus 3.1 months in the control arm (investigator choice of therapy; n=103), showing highly statistical (HR 0.42, p<0.0001) and clinically meaningful benefit that mirrored Ph2 results (7.0 months mPFS). Further, overall response rate (ORR) of 37.1% and median duration of response (mDOR) of 6.8 months compared to Ph2's 34.1% and 9.0 months, respectively. On the latter, we note management commentary around 10 months duration of therapy is consistent with our assumptions/expectations, and that mDOR could potentially improve with further follow-up (beyond current ~10 months). Safety looked in line with prior studies, with the most common Gr3+ adverse events (diarrhea, syncope, and hypotension) described as manageable with single-digit percentage of serious treatment-related adverse events in the daro combination arm. Notably, IDYA said overall survival (OS) was trending positively thus far, and given PFS consistency between datasets, as well as control arm data that suggests OS in the ~13 month range, we are positive ahead of planned interim OS readout expected in ~2027 (we do not expect further data on OS at ASCO).

Overall, we are comfortable with the consistency of data and profile thus far (we model $950M peak sales for mUM with 90% probability of success). Relative to the detailed data at ASCO, we will be looking for: i) details on key patient background characteristics, including LDH, metastases location (hepatic only vs extrahepatic or both), and ECOG status; ii) safety details, particularly on Gr3+ events; iii) details on efficacy beyond Kaplan-Meier PFS estimate (i.e., waterfall/swimmer plots); iv) potential for longer follow-up to improve further on mDOR/mPFS.

Immunome (IMNM, Buy, Salveen Richter)
RINGSIDE: A phase 3 randomized, placebo-controlled trial of varegacestat for treatment of progressing desmoid tumors

IMNM will present full results from the Ph3 RINGSIDE study of gamma-secretase inhibitor varegacestat in desmoid tumors in an oral presentation. Recall, IMNM previously shared positive Ph3 topline data demonstrating a statistically significant progression-free survival (PFS; hazard ratio (HR) = 0.16; p<0.0001) benefit vs. placebo, objective response rate (ORR) of 56%, and tumor volume reduction of 83%, solidifying varegacestat's best-in-class position over Merck KGaA's Ogsiveo. The ASCO abstract additionally contains key secondary endpoints, including quality of life impacts, where we note all alpha-controlled secondary endpoints demonstrated statistically and clinically significant superiority for varegacestat vs. placebo. On the key endpoint of pain relief, varegacestat demonstrated a statistically significant difference of -2.42 vs. placebo per the Widespread Pain Index (WPI).

Exhibit 1: RINGSIDE Ph3 Trial Outcomes

	VAR (n=79)	PBO (n=77)	HR (95% CI) or Difference; P value
Median PFS (95% CI) - radiographic, months	NE (NE, NE)	24.9 (13.8, NE)	0.16 (0.07, 0.38); P<0.0001
Confirmed ORR, n (%)	44 (55.7)	7 (9.1)	P<0.0001
TV change (cm^3) at Week 24, LS mean (SE)	-109.6 (40.64)	122.8 (42.72)	-232.4 (57.39); P<0.0001
WPI (pain) change at Week 12, LS mean (SE)	-2.24 (0.27)	0.18 (0.27)	-2.42 (0.37); P<0.0001
Median best % change in TV*	-83.4	11.3	*
1-year PFS, % (95% CI)*	94.2 (85.3, 97.8)	65.6 (52.3, 76.0)	*
2-year PFS, % (95% CI)*	88.9 (77.9, 94.6)	56.7 (42.6, 68.6)	*

LS, least square; SE, standard error.

*Not alpha-controlled endpoint.

Source: Company data

Overall, the data further demonstrates varegacestat's best-in-class profile in our view, where we note varegacestat demonstrated 94.2%/88.9% 1-year/2-year PFS rates, vs. 85%/76% for Ogsiveo in the Ph3 DeFi study. Additionally, after 10 28-day cycles of Ogsiveo, patients saw a -1.5 point mean change from baseline in their average worst pain intensity score (per the BPI-SF; Brief Pain Inventory - Short Form). We see further differentiation per varegacestat's once-daily dosing vs. twice-daily for Ogsiveo in the context of physician/patient preference for the easier regimen, and on ovarian toxicity, observed in ~55.6% of premenopausal women vs. 75% for Ogsiveo. An NDA for varegacestat was submitted in 2Q, and IMNM plans to submit a Marketing Authorization Application to the European Medicines Agency for varegacestat by

YE26. Given the profile, we anticipate a stronger launch relative to Ogsiveo and model for global peak sales of $1.6bn in 2037.

Gilead (GILD, Neutral)

NAPISTAR 1-01: Results of phase 1 dose escalation of monotherapy with TUB-040, a novel NaPi2b-targeting exatecan ADC, in patients (pts) with platinum-resistant ovarian cancer (PROC)

Background. Recall NaPi2b is overexpressed in high-grade serous ovarian cancer and non-small cell lung cancer (NSCLC). TUB-040 is a DAR8 ADC targeting NaPi2b, comprising a humanized Fc-silenced IgG1 mAb conjugated to exatecan via a cleavable, cysteine-selective, stable, solubility-mediating P5 linker providing excellent stability and biophysical ADC properties. In preclinical studies, TUB-040 induces potent antigen-specific cytotoxicity and demonstrates strong bystander activity.

NAPISTAR 1-01 is a phase 1/2a study in biomarker-unselected pts with PROC and NSCLC. TUB-040 was administered Q3W in dose escalation (range 0.5-5.3 mg/kg) to pts with PROC until progression or unacceptable toxicity. As of Dec 1, 2025, 67 PROC pts received TUB-040 for a median of 10 cycles (1-25), median duration of exposure was 213 days (21-546), and 42 (63%) pts were ongoing. Median age: 62 years (34-81), ECOG PS 0-1, median prior lines: 4 (1-7), prior treatment included bevacizumab (84%), PARPi (76%), and mirvetuximab soravtansine (13%).

Efficacy. Between dose levels 1.67–3.3 mg/kg, 46 pts were evaluated for efficacy. The uORR was 63% [95% CI, 47.5-77.2] and cORR was 60.9% [95% CI, 45.3-75.1] (RECIST; v1.1), including two cCRs. The majority of responses, 90% (26/29), were ongoing. Disease control rate was 96% [95% CI, 85.2-99.5]. Among CA-125 evaluable pts (N=42), CA-125 response occurred in 81% (34/42) [95% CI, 65.6-91.5]. cORRs were similar across subgroups, including: ≥4 prior lines of therapy (cORR=71%), prior exposures to bevacizumab (62%), mirvetuximab soravtansine (63%) or PARPi (67%). Five pts with stable disease remain on treatment and eligible for response.

Exhibit 2: Summary of results

	1.67 mg/kg (N=10), n (%)	2.1 mg/kg (N=12), n (%)	2.50 mg/kg (N=12), n (%)	3.3 mg/kg (N=12), n (%)	Total (N=46), n (%)
Complete response	1 (10)	0	1 (8)	0	2 (4)
Partial response	6 (60)	7 (58)	7 (58)	6 (50)	26 (57)
Stable disease	2 (20)	5 (42)	3 (25)	6 (50)	16 (35)
Progressive disease	1 (10)	0	1 (8)	0	2 (4)
Overall responses (PR + CR)	7 (70)	7 (58)	8 (67)	6 (50)	28 (60.9)
Gr≥3 neutropenia	0	2 (17)	4 (33)	6 (50)	12 (26)
Gr≥3 anemia	0	0	1 (8)	5 (42)	6 (13)
Gr≥3 thrombocytopenia	0	0	1 (8)	1 (8)	2 (4)

Source: Company data

Safety & tolerability. Between dose levels 1.67-3.3mg/kg (N=46), the most common all-grade TEAEs were nausea (78%), fatigue (54%), neutropenia (43.5%), anemia (37%), constipation (34%), diarrhea (33%), vomiting (28%), alopecia (28%), and decreased appetite (26%). Gr≥3 heme TEAEs by dose are in Table 1. There were no fatal TEAEs or treatment discontinuations due to TEAEs. Three pts (6.5%) experienced Gr1 pneumonitis, which resolved.

Overall, we view the data as encouraging and broadly in-line with the previous update at ESMO – specifically, ORR of ~63% (vs. ~59% at ESMO) and DCR of 96% (vs. 97% prior) and similarly manageable safety/tolerability profile (note the MTD was previously determined to be 4.4mg/kg), and see the drug as one of the leading emerging therapies in ovarian cancer. Dose optimization is currently ongoing. GILD has noted the potential for a registrational study initiation in FY27.

Exhibit 3: Select competitor drugs in ovarian cancer

Therapy	Class	Patient Population	Confirmed ORR
TUB-040	ADC (NaPi2b)	NaPi2b-expressing PROC	61%
ETX-19477	PARG Inhibitor	BRCA-mutated PROC	57%
Raludotatug Deruxtecan (R-DXd)	ADC (CDH6)	CDH6-expressing PROC	50.5%
QLS5132	ADC (CLDN6)	CLDN6-expressing PROC	50%
Avutometinib + Defactinib	RAF/MEK + FAK	KRAS-mutated LGSOC	44%
Lifyorli + Nab-paclitaxel	GR Antagonist + Chemo	Biomarker-agnostic PROC	36.9%
INCB123667	CDK2 Inhibitor	CCNE1-overexpressing PROC	33.3%
Keytruda + Paclitaxel	IO + Chemo	PD-L1+ (CPS ≥ 1) PROC	~18%

Source: Company data

Updated overall survival, safety, and neurologicunction outcomes from a phase 1 trial of bivalent chimeric antigen receptor (CAR) T cell therapy in recurrent glioblastoma (GBM).

Background. Recall GILD previously reported the safety, bioactivity, and preliminary efficacy of bivalent CAR T cells targeting EGFR and IL13Rα2 in 18 patients with recurrent GBM (Bagley, et. al, Nat Med 2025). Given that medianollow-up time was only 8.1 months at the time of the data cut-offor that publication, GILD is reporting updated overall survival (OS) and safety data with longerollow-up time, as well as neurologic unction outcomes.

Eighteen patients with recurrent EGFR-amplified GBM were enrolled using a 3+3 design (dose levels: 5.0 x 10^6, 1.0 x 10^7, and 2.5 x 10^7 cells). Patients received a single intracerebroventricular (ICV) dose of CART-EGFR-IL13Rα2 cells. OS was defined as the time from the date of initial study treatment to the date of death from any cause, or censored at the last date of contact if the patient was not known to have died at the date of analysis cut-off (January 16, 2026). To capture changes in neurologicunction over the course of the trial, patients were assessed prospectively using the Neurologic Assessment in Neuro-Oncology (NANO) scale. NANO is an objective clinician-reported outcome of neurologicunction scored on nine domains, with a higher score indicating worse neurologicunction. NANO scores were assessed at baseline prior to CART (day 0), on days 1, 4, 7, 10, 14, 21, and at the 1-month and 2-month visits post-CART.

Efficacy. With medianollow-up time of 18.5 months, median OS was 12.0 months (95% confidence interval, 7.4 – 23.2 months) with 3 patients surviving greater than 18 months.

Safety. Other than one patient with prolonged grade 1 neurotoxicity as previously described, no prolonged, late-onset, or unexpected toxicities were obs longerollow-up time, including no evidence of on-target o ff-tumor tox secondary cancers. On day 1 post infusion, an increase in NANO scores (mean increase in NANO score from baseline of 1.9; p=0.09), which reso by day 4. Patient NANO scores were unchanged from baseline at one m

change 0.41; p=0.998) and two months (mean change 0.54; p=0.992) post infusion. Those who underwent retreatment with a second dose of CAR-T cells at the time of tumor progression (n=7) did not experience an increase in NANO score on day 1 (mean change 0.33, p=0.99), despite having a significant increase on day 1 following the first infusion (mean change 2.9, p=0.008).

Overall, we view the update as encouraging – while acknowledging the small data set, the overall survival data represents a potentially clinically meaningful improvement vs. current standard of care (OS of ~12 months vs. ~8 months for chemo/ bevacizumab), as well as a potentially significant step for CAR T therapy in solid tumors more broadly.

Moderna (MRNA, Neutral)
Individualized neoantigen therapy intismeran autogene (intismeran) plus pembrolizumab (pembro) in resected melanoma: 5-year update of the KEYNOTE-942 study

The abstract includes detailed five-year data from the Ph2b study of MRK-partnered (covered by Asad Haider) mRNA-based individualized neoantigen therapy (INT) intismeran autogene in resected high-risk melanoma. Recall, MRNA presented 5-year topline data in January, with the combination of intismeran plus Keytruda leading to a reduced risk of recurrence or death by 49% (HR=0.510; [95% CI, 0.294-0.887], one-sided nominal p=0.0075) versus Keytruda alone (recurrence-free survival (RFS), the primary endpoint), a clinically meaningful and durable result. The following was newly reported per the abstract: 1) RFS rates of 68.8% (95% CI, 56.3%-78.3%) for the intismeran combination arm, versus 49.1% (95% CI, 33.3%-63.0%) for the Keytruda monotherapy arm; 2) distant mestastasis free survival (DMFS) risk reduction of 59% (HR 0.41, roughly comparable to the ~3 year data which had an HR of 0.384); and 3) a trend for improved overall survival (OS; HR 0.47). The OS rate at 5-years was 92.2% for the intismeran combination arm versus 71.3% for the Keytruda arm alone – notably the Keytruda arm has diverged from the ~3-year data, whereby the combination arm had an OS of 96.0% vs. 90.2% in the Keytruda arm. Importantly, the safety profile of intismeran was consistent with prior analyses.

Overall, following the 5-year topline data disclosure in January on RFS, we are encouraged by the detailed data including maintenance of DMFS, noting it is a prognostic marker of longer-term outcomes, and the trend for improved OS over Keytruda alone, which appears meaningful. We next look to Ph3 intismeran data in adjuvant melanoma likely in 2026 (pending event accrual), where translation of the Ph2 data to the larger Ph3 study is key (we note RFS is also the primary endpoint in the Ph3 study) and investor attention centers on the study design and understanding the powering assumptions for the interim analysis (which MRNA has not disclosed).

Syndax Pharmaceuticals (SNDX, Buy)
SNDX will have four Revuforj (revumenib) abstracts at ASCO, adding to 12 abstracts accepted at EHA, that cumulatively: i) add to the growing body of data on maintenance use, which could act as a tailwind particularly in the KMT2Ar population as more patients return to therapy post-stem cell transplant (currently ~45%, but management cites 70-80% as appropriate candidates); ii) support differentiation vs. competitor menin inhibitors with PK data that highlights ease of use; iii) highlight trial designs in the newly diagnosed setting, where SNDX estimates a $5B addressable market (vs. $2B TAM

in r/r AML).

- **Maintenance data.** SNDX has an oral presentation on revumenib as maintenance therapy in 21 AML patients (16 KMT2Ar, 4 NPM1m, 1 NUP98r) post-stem cell transplant. The abstract showed favorable outcomes vs. historical data, including 89% 1-year and 2-year survival (vs. 60% and 51%, receptively), with a median 6.7 months median duration of therapy in maintenance with 18.2 months median follow-up. Thrombocytopenia was the most common adverse event, requiring dose modification in 48% of patients and causing discontinuation in 10%, with the abstract noting no other significant toxicities observed.
- **PK data.** A poster on revumenib's pharmacokinetics (PK), including differentiating properties that allow i) administration with gastric acid reducing agents (highly prevalent in AML) without the risk of reduced efficacy (vs. Komzifti's drug-drug interactions with antacids/proton pump inhibitors on label), and ii) ensure optimal exposure in the presence of strong CYP3A4 inhibitors via a clear revumenib dose adjustment strategy, and iii) administration of revumenib with low-fat meals (vs. Komzifti's food effect).

Regeneron Pharmaceuticals (REGN, Buy)
First results from the Phase 1/2 LINKER-AL2 trial evaluating Lynozyfic (linvoseltamab) in adults with second-line-plus systemic amyloid light chain (AL) amyloidosis

REGN released initial efficacy and safety data from the Ph1/2 LINKER-AL2 study of Lynozyfic (linvoseltamab, BCMAxCD3) monotherapy in patients with relapsed or refractory systemic light chain amyloidosis (AL), a rare disease impacting plasma cells. In the preliminary analysis, 20 patients received Lynozyfic 80 mg (n=7) or 240 mg (n=13) subcutaneously. At median follow-up of 9.5 months, Lynozyfic had no observed dose-limiting toxicities, and we highlight the following: 1) hematologic responses were observed in all patients; at the lower-dose 100% of patients achieved a very good partial response (VGPR) or better, and 71% (n=5) achieved a CR; at the higher-dose 100% achieved a CR - REGN noted responses were durable, 2) there were notable responses associated with improved renal (73%; n=8) and cardiac (50%; n=4 of 8 by biochemical response) organ function, with no patients experiencing major organ deterioration. On safety, one patient at the higher dose discontinued treatment due to AEs (pneumonia) after achieving CR, and one patient in the higher dose cohort with a hematologic CR experienced sudden death in the context of cardiac amyloidosis; and one patient in the lower dose cohort with pre-existing coronary artery disease had fatal ventricular fibrillation within 24 hours of coronary artery stent placement, assessed as unrelated to Lynozyfic by the investigator.

REGN estimates this line of therapy can address a US population of ~1,800, and we are overall optimistic on REGN's development plan for Lynozyfic into earlier multiple myeloma treatment lines, precursor and related indications including the above which represent upside to our model. The Ph2 portion of the trial with registrational intent is underway.

Valuation and Risks

GILD (Neutral): Our 12-month price target of $130 is based on a 100% DCF analysis (3% TGR, 8% WACC). Downside risks: Clinical or regulatory failures or delays (in particular, for the long-acting HIV portfolio); Headwinds/disruptions to HIV market; Weaker than expected Biktarvy or Yeztugo sales growth; Success of competitor drugs. Upside risks: Market growth and/or penetration greater than our assumptions; Less pricing pressure from generics in HIV market in 2H of decade; Clinical or regulatory failures or delays of competitor drugs.

IDYA: We rate IDYA at Neutral with a 12-month price target of $36 based on a DCF that assumes a 13% discount rate and 3% terminal growth rate, which we believe are appropriate given their late-stage, clinically de-risked lead asset, as well as their early-stage pipeline. Key upside risks include: better-than-expected efficacy for darovarsertib in Ph2/3 (PFS data), clear and straightforward path to registration for the adjuvant uveal melanoma setting for darovasertib, and potential for best-in-class efficacy and safety data for one or more pipeline products. Downside risks include: negative clinical updates for darovasertib, slower-than-expected development of pipeline assets, and failure to execute on business development.

IMNM (Buy): Our 12-month PT of $35 is based on a blended 85%/15% risk-adjusted DCF value of $27 (WACC of 17% and TGR of 5%) and a theoretical M&A component of $83 (11x 2031E sales following 2 full years of IM-1021 sales). Downside risk: Clinical/technology risk: If IMNM's targeted oncology programs fail to demonstrate sustained and durable benefit, their long-term potential may be inhibited with limited physician uptake, and unexpected safety issues or clinical delays may push launch timelines. Competitive risk: competitor assets could advance through clinical development ahead of expectations or generate data that appears superior to IMNM's assets. Regulatory risk: inability to secure regulatory approval for indications or territories, regulatory requirements and timelines may affect trial scope and timelines. Commercial risk: despite receiving marketing approval, IMNM's product may fail to achieve commercial success given potential manufacturing difficulties as a result of production scale up. Financing/dilution risk, and lower-than-expected sales would also provide downside risk to our estimates.

MRNA (Neutral): Our 12-month updated PT of $49 is based on a 100% DCF value (12% WACC and 3% TGR). Upside risks: Commercial risk - higher than anticipated sales and penetration into patient populations, earlier-than-expected approval timelines from the oncology programs, other pipeline success and competitive failures. Downside risks: Failure to demonstrate clinical proof of concept across additional modalities or across additional oncology indications, IP risk, manufacturing difficulties and financing/dilution, failure to achieve the projected commercial profile, physician/payor pushback on use and coverage, approval of competitor drugs.

REGN (Buy): Our 12-month PT of $968 is based on a 100% DCF value (8% WACC, and 3% TGR). Risks: Lower-than-expected sales would provide downside risk to our estimates, unexpected safety issues or clinical delays for products or label expansions would provide downside risk, competition will likely intensify in DME/wet AMD, notably from ROG and new agents, and greater uptake from these may lead to a greater market share erosion from Eylea than modeled. Lack of success for pipeline drugs: Pipeline

programs may be unsuccessful or not achieve regulatory approval. Medicare Part B reform: Given the higher prevalence of wet AMD and DME in elderly people, Eylea sales are exposed to risk from future potential reforms. Unfavorable reimbursement could be a source of downside risk to our estimates.

SMMT (Buy): Our 12-month PT of $41 is based on a blended 85%/15% risk-adjusted DCF value of $35 (WACC of 18% and TGR of 2%) and a theoretical M&A value of $73 (11x 2031E sales). Downside risks: Clinical, technology and manufacturing risk - data generated by partner Akeso in China may not translate to SMMT's global clinical studies; U.S.-China trade relations may adversely impact supply chain operations; unexpected safety issues or clinical delays may push launch timelines. Regulatory risk - failure to secure regulatory approval for indications or territories could impact commercial success and would pose significant downside risk to our sales estimates. Competitive risk - competitor PD-1/L1xVEGF assets could demonstrate superior data, or advance through clinical development ahead of expectations. Financing risk/dilution.

SNDX (Buy): Our 12-month price target is $34. Our price target is based on a DCF valuation which assumes a 12% discount rate and 3% terminal growth rate, consistent with our commercial coverage and the range of expansion opportunities for Revuforj not currently modeled in 1L AML. Key risks include: less-than-expected uptake of Revuforj in KMT2Ar acute leukemias, better-than-expected competitor readouts in the menin inhibitor class, and failure to execute on first-line clinical development programs for revumenib.

Disclosure Appendix

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We, Salveen Richter, CFA, Corinne Johnson, Mark Aleynick, Ph.D., Matt Dellatorre, Ph.D., Elizabeth Webster, Ph.D., Tommie Reerink, CFA, Kevin Strang, Ph.D., Shrunatra Mishra, Erik Wong and Lydia Erdman, hereby certify that all of the views expressed in this report accurately reflect our personal views about the subject company or companies and its or their securities. We also certify that no part of our compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

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Contributing Authors: Salveen Richter, CFA Goldman Sachs & Co. LLC, Corinne Johnson Goldman Sachs & Co. LLC, Mark Aleynick, Ph.D. Goldman Sachs & Co. LLC, Matt Dellatorre, Ph.D. Goldman Sachs & Co. LLC, Elizabeth Webster, Ph.D. Goldman Sachs & Co. LLC, Tommie Reerink, CFA Goldman Sachs & Co. LLC, Kevin Strang, Ph.D. Goldman Sachs & Co. LLC, Shrunatra Mishra Goldman Sachs India SPL, Erik Wong Goldman Sachs & Co. LLC, Lydia Erdman Goldman Sachs & Co. LLC.

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