

Americas Healthcare: Biotechnology: Takeaways from our lunch with Endocrinologist on key launches, recent data

We hosted a lunch with an adult endocrinologist, Dr. Aren Skolnick (~350 monthly patients under care), where we discussed a broad range of endocrine conditions including: hypoparathyroidism, Congenital Adrenal Hyperplasia, Post-bariatric Hypoglycemia, Prader-Willi syndrome, Hypothalamic Obesity, achondroplasia, acromegaly, and Graves' disease/Thyroid Eye disease. Across indications, the physician is using novel therapies in a handful of patients noting good experience to-date with Yorvipath, Crenessity, and Vykat in particular, despite insurance/reimbursement hurdles which he cited are an issue across high price point rare disease therapies that his office is navigating, often with significant support from manufacturers. With respect to development stage candidates, the doctor sees i) potential for atulmenant to be differentiated via convenience/mechanism of action in CAH (particularly for patients not well managed on Crenessity), ii) recent setmelanotide data in PWS as unprecedented with respect to weight loss, and compelling on quality of life endpoints, iii) significant unmet need in PBH that could be addressed by avexitide (with a 50% absolute reduction in L2/L3 events the bar for clinical meaningfulness), and iv) encouraging evidence of clinical activity with canvuparatide, noting responder analyses in clinical trials do not reflect real-world treatment practice.

Please see within for additional details.

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Key takeaways

Hypoparathyroidism (ASND, MBX)

Weekly-dosing is preferable, but real-world adoption is dictated by the comprehensive data profile.

- The KOL manages roughly ten HPT patients in his clinic, of which half of the patients were well managed and five patients were currently treated with Yorvipath.
- The doctor noted patients who have escalated to Yorvipath don't mind the daily injection frequency, and were overall satisfied to taper off the supplements and were still able to sustain blood calcium levels.
- Yorvipath were initially prescribed in the severe and poorly managed patients

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(have hypocalcemia events in regular basis/ kidney issues) or are hospitalized, and is now moving towards use in the moderately controlled population.

KOL sees a 50% response rate threshold for the weekly-injectables.

- On the recent MBX once-weekly canvuparatide 52-week data update that showed a decline in responder rate to 57% vs. 79% at 26 weeks (see [note](#)), the KOL noted Yorvipath still stands as the gold standard in terms of treatment (recall, Yorvipath Ph3 data demonstrated stable efficacy of c.80% over 26-52 weeks). However, the KOL sees a 50% response rate as a reasonable trade-off threshold for a weekly-injectable, and noted that response criteria in clinical studies which limit PRN use do not reflect real-world treatment practice and thus should be evaluated in the context of the totality of clinical benefit.
- Canvuparatide is most likely to capture patients who are stable on daily dosing and want a less-frequent dosing interval. Additionally, he might start new patients who otherwise wouldn't tolerate daily injections. Ahead, he wants to monitor if the efficacy in longer follow-ups sustains.
- With respect to pricing, the KOL thinks canvuparatide could be priced at a premium, though expects some payor hurdles.

Congenital Adrenal Hyperplasia (NBIX, CRNX)

Positive experience with Crenessity, atumelnant could address unmet need via differentiated mechanism of action

- Our expert is treating around 20 CAH patients and has been using Crenessity in three of his female patients to better control high androgen levels. Use has been limited thus far based on patient symptom burden (including Cushingoid symptoms), while some patients do not have the classic form of CAH and others have not been to the office since Crenessity's launch (1-2x visits per year is standard). The three patients on Crenessity have been able to lower their GC usage while achieving lower weight and glucose levels. Reimbursement has been manageable, with NBIX helpful in navigating through documentation and prior authorization requirements, and it usually only takes 3-4 weeks for payers to approve patients for Crenessity.
- The physician found the recent 2-year update on bone effects for Crenessity to be useful since younger patients are still accruing their peak bone mass and can further support use in these patients. The cardiometabolic benefits were already expected. However, the doctor noted that the 2x daily dosing requirement for Crenessity and lack of impact on androgen (stabilization vs. reductions observed) are limitations of the medication. These drawbacks could incentivize the expert to use atumelnant when it is approved due to its once daily oral dosing and the potential to lower A4 levels to below the upper limit of normal (ULN) based on its differentiated MC2R antagonist mechanism, particularly among treatment naïve patients and those who are symptomatic or not well controlled on Crenessity. The expert mentioned that two of his three patients on Crenessity could potentially benefit from switching to atumelnant, but acknowledged this is a small sample size.
- With respect to liver tox findings previously observed with atumelnant, the physician

is not concerned given the incidence is low and cases seem mild. However, if future results suggest that LFT levels exceed 3x ULN this could present a reason for concern.

Post-Bariatric Surgery Hypoglycemia (AMLX)

Significant unmet need in PBH population, estimated at 15-20% of patients and reflected in patient demand for new therapeutic options

- The physician characterized this as a very high unmet need population, noting patient engagement among the highest across his practice with respect to patients seeking new and better treatment options and frustration with current standard of care. He noted that standard of care options like diazoxide do not work well, and come with significant quality of life burden; while he has tried GLP-1 agonists (predicated on slowing gastric emptying), these do not work particularly well and a significant portion of patients require new options.
- Of ~30 patients under his care, the doctor noted ~40% are not well managed with dietary modifications or existing therapy and at least 15-20% are having regular, severe, hypoglycemia events. The latter population would be the most obvious candidates for treatment initiation on approval of avexitide, and we note that this aligns closely with our own estimates that ~30K patients would form the initial addressable market (relative to 160K patient prevalence).
- Ahead of Ph3 data, the KOL noted a 50% absolute reduction in Level 2/Level 3 events would be compelling with respect to efficacy, which compares to assumptions underpinning trial design of a 35% placebo-adjusted improvement and expectations for ~50% placebo response.
- While the physician anticipates documentation will be required for insurance coverage of avexitide, if approved for PBH, he does not see this as a meaningful hurdle for treatment adoption noting classification of PBH vs. other forms of hypoglycemia is already standard practice.
- In addition to PBH, the KOL sees some promise in the use of avexitide or another GLP-1 antagonist for the treatment of other forms of hypoglycemia.

Prader-Willi Syndrome (NBIX, CRNX, RYTM)

Enthusiasm for both Vykat and setmelanotide in this very difficult to treat patient population

- The physician is currently using Vykat in a handful of patients with plans to inform his broader population of the new option, noting his experience to-date reflects improvement in patient and especially caregiver quality of life. The latter is of particular importance to him, and will inform plans to expand use of this agent over time. With respect to safety, while the doctor is monitoring for edema/hyperglycemia, and may restrict the drug from patients at risk of these effects, he has not observed significant side effects to-date. Insurance reimbursement has been a moderate hurdle to treatment adoption.
- Regarding recent data from RYTM in PWS, the physician commented that weight loss

results were unprecedented relative to this difficult to treat and highly metabolic resistant population, noting GLP-1s in the population may deliver 1-3% weight loss over a year. Moreover, benefit on HCQT was described as impressive, and consistent with his experience using Vykati, the doctor sees these quality of life endpoints as particularly important for the population of patients with PWS.

- To that end, he would hope to see benefit on HCQT prioritized in registrational studies, though effect on both weight and quality of life endpoints would be a best case scenario (noting Vykati does not improve weight). In a registrational study evaluating weight changes, the doctor noted most patients reach stable (but elevated) weight in their late 20s/early 30s, and he would not anticipate significant weight gain in those age groups (when considering potential placebo performance).
- If reimbursed by insurance, the physician would find combination use of setmelanotide with Vykati as compelling given distinct mechanisms of action.

Hypothalamic Obesity (RYTM)

- The physician has not yet prescribed Imcivree for HO, noting patients are seen only 1-2x per year, but plans to put ~20% of patients on therapy near-term based on their weight/refractoriness to therapy and comorbidities. Given this is an adult population, the physician noted that GLP-1 reimbursement is relatively straightforward and provides up to 15% weight loss in some patients.

Thyroid Eye Disease / Graves' Disease (VRDN, ROIV/IMVT)

- We touched briefly on Graves' disease, where the physician noted ~25% of his patients are not well-controlled on anti-thyroid medications and another portion are controlled but cannot get off of ATDs, with both likely to be candidates for advanced therapies in the indication like FcRns or IgG degraders. He would anticipate a mix of chronic use and intermittent treatment with these agents, similar to current practice with ATDs.

Achondroplasia (ASND, BBIO, BMRN, TYRA)

Oral options could meaningfully expand treatment for achondroplasia

- The KOL manages ten pediatric ACH patients, which are a mix of hereditary and de novo cases. Two of his patients are currently on Voxzogo. With respect to limited adoption to-date, he sees daily injections as a huge burden in pediatric care, and thinks weekly Yuviwel could bring more patients in for treatment. Oral drugs would be a good fit for ACH when introduced (such as infigratinib and dabogratinib), and note that some patients might be deferring treatment for the orals to launch.
- The KOL noted families are sometimes hesitant to start new medications, but thinks the practice will add 3 patients on infigratinib vs 3-4 on injections out of the 10 patients in his care.
- FGFR3 biology: The KOL cares about the hyperphosphatemia associated with FGFR effects. That said, he thinks it is manageable and overall not a clinical deterrent to getting on therapy. While early, the KOL thinks dabogratinib could be comparable or slight better than infigratinib in a pivotal study given greater selectivity for FGFR3.

Acromegaly (CRNX)**Palsonify used in 10% patients but half may qualify, fasting could be challenging to manage**

- Our expert is treating around 20-25 acromegaly patients and has been using Palsonify for 2-3 of these patients. The limited usage is due to short time since approval, payers requiring step edits through 2-3 drugs due to Palsonify's high list price, and availability of oral Mycapssa since 2020. The expert's practice has a specialized pituitary center which is why he is able to treat more acromegaly patients. Compared to CAH, acromegaly has many effective treatment options.
- Palsonify's 1-hour post-dose fasting requirement is somewhat problematic since many patients have transphenoidal resection and 80% of these patients have thyroid deficiencies that require Synthroid treatment that also have fasting requirements. The various fasting requirements from these treatments are challenging to manage for patients. However, the expert will increase use in the future and 10 of his patients could qualify for Palsonify.

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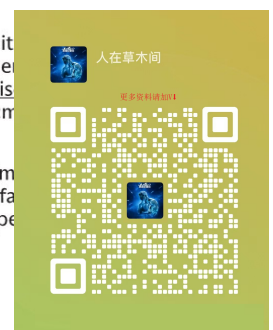
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