China Biotech

Read-Through: Firmonertinib Global Ph3 Failure Highlights Trial Design Risk, Rather than Asset-Origin Risk

Healthcare

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Firmonertinib, an EGFR inhibitor drug out-licensed to US biotech ArriVent from a China biotech company in 2021, recently failed in a global Ph3 trial. According to ArriVent, whose shares fell ~47% on 6 October (vs. XBI down 3.4%), its Ph3 FURVENT trial in first-line EGFR exon 20 insertion–mutant NSCLC (non-small cell lung cancer) missed its primary endpoint of PFS (progression-free survival), with firmonertinib 240 mg delivering only a modest BICR (blinded independent central review)-assessed PFS advantage over chemotherapy (news). While the readout is clearly a setback, we do not view it as a broad negative read-through for China-originated innovative drug out-licensing trend. Instead, we see the outcome as largely trial-specific: a stronger-than-expected control arm performance likely compressed the apparent benefit and made statistical success harder to achieve. This Ph3 failure reinforces a simple message that promising assets still need high-quality global trial design and execution. We think partnering with an experienced MNCs (multinational corporations) or a proven clinical development team may merit a premium versus less experienced biotech or NewCo platforms.

- **FURVENT missed its primary endpoint despite evidence of firmonertinib activity**: The global Ph3 trial in previously untreated EGFR exon 20 insertion-mutant NSCLC showed BICR-assessed median PFS of 11.0 months for firmonertinib 240 mg versus 9.5 months for chemotherapy, with HR of 0.75 and p=0.0654. Additionally the 240-mg arm also showed a higher confirmed objective response rate, at 60% versus 33% for control, but the PFS separation was not sufficient to achieve statistical significance. Management flagged the non-primary end-point Investigator-assessed median PFS of 7.1 months which appeared more favorable for firmonertinib. ArriVent reported no new safety signals in this Ph3 trial.
- **A stronger-than-expected control arm performance likely narrowed the room for statistical success.** The 9.5-month BICR-assessed control-arm PFS left only a 1.5-month median PFS delta for the 240-mg dose, which likely reduced the study's ability to demonstrate a statistically significant treatment effect. We suspect the trial may have been designed around a lower control-arm PFS assumption or a larger expected treatment effect, although this remains our interpretation rather than a confirmed explanation, as ArriVent has not disclosed the original statistical plan. Importantly, this was not simply an under-enrollment issue, as the FURVENT trial enrolled 398 patients versus a target of approximately 375. We would also note that firmonertinib was approved in China for 2L EGFR exon 20 insertion-mutant NSCLC based on a Ph2 single-arm trial. The drug has not undergone a China Ph3 trial in 1L EGFR exon 20 insertion–mutant NSCLC, making direct comparisons with China's clinical experience less straightforward.
- **We see a limited read-through to China biotech, but partner quality may matter more.** While the miss may somewhat weigh on near-term investor sentiment towards China-originated out-licensed drug assets, we view the outcome as idiosyncratic and trial-specific rather than a broad negative signal on China drug innovation. The result highlights that even a clinically active

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asset needs a global pivotal trial design capable of demonstrating benefit against the control arm actually observed. In our view, this supports a potential premium for overseas partners with established global trial design, regulatory, and execution capabilities versus less experienced biotechs or NewCos, although partner reputation alone cannot eliminate development risk. For example, we think Kelun-Biotech chose a strong MNC partner Merck for its sac-TMT, which has already announced the first global Ph3 success of sac-TMT in TroFuse-005.

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