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# Big biotech's upcoming clinical priorities

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## Key catalysts lie ahead for Amgen, Argenx, Point Biopharma and Novo Nordisk.

Following our look at some important upcoming readouts for big pharma, this series continues with notable clinical results expected for biotech companies with a market cap of at least $1bn.

Amgen will report small cell lung cancer data on tarlatamab, which targets DLL3, and on Lumakras in colorectal cancer. Argenx is moving Vyvgart Hytrulo towards a new market, while Point Biopharma hopes to take on Novartis with its radiopharmaceutical PNT2002. Lastly, Novo's cardiovascular outcomes study with Wegovy is due to read out soon, and could provide an important label boost.

### Amgen tackles oncology

**Amgen** will see two cancer readouts in the second half of the year. Dellphi-301, a potentially registrational phase 2 study of **Tarlatamab**, a bispecific T-cell engager (Bite), will yield results. The trial is in patients with small cell lung cancer who have received two or more lines of therapy. The project targets DLL3, which is said to be highly expressed in SCLC; this was the target of Abbvie's failed antibody-drug conjugate Rova-T.

In tarlatamab's phase 1 study in heavily pretreated patients there was a confirmed objective response rate of 23% and a median duration of response of 13.0 months.

Some second/third-line standard treatments in SCLC have remained unchanged for a while and, according to Wells Fargo analysts, the bar to beat is median overall survival of five to eight months, with around 25% of patients responding.

An earlier study showed relatively low rates of grade 3+ cytokine release syndrome, neurologic events and neutropenia. This safety profile is encouraging, as other bispecifics have had issues with cytokine release syndrome, a side-effect typically associated with Car-T therapy.

Amgen's other oncology dataset concerns **Lumakras plus Vectibix** in Codebreak-300, a phase 3 third-line colorectal cancer study that potentially sets up competition for Mirati's Kras inhibitor Krazati. Krazati demonstrated impressive data at last year's Esmo, with an Erbitux combination producing a 46% confirmed objective response rate in the Krystal-1 trial, in patients with median 3 prior therapies. In Amgen's earlier Codebreak-101 study, in a less heavily treated population, the ORR was 30%.

Mirati is expected to complete the filing for Krazati in third-line colorectal cancer this year.

### New market

As mentioned in our big pharma catalyst story, there is a lot going on in the anti-FcRn space. For **Argenx** a big readout is coming up in chronic inflammatory demyelinating polyneuropathy (CIDP), a potentially large new setting.

Argenx's project, subcutaneous efgartigimod, is now known as **Vyvgart Hytrulo** after gaining FDA approval last month in generalised myasthenia gravis. The intravenous version has been on the market since early 2022.

Data from the Adhere study in CIDP is now expected in July. As previewed by *Vantage*, for Vyvgart Hytrulo to look at least as good as immunoglobulins, the standard of care in CIDP, the delta between active and placebo on relapse rates needs to approach 40%.

**To the point**

**Point Biopharma** is pitting **PNT2002** against Novartis's radiopharmaceutical Pluvicto in pre-chemo metastatic castration-resistant prostate cancer. Glimpses of efficacy have already been seen with PNT2002, with median rPFS of 11.5 months in the 27-patient safety and dosimetry lead-in cohort for the Splash trial. Now data are due from the randomised part of this study.

Assessing how PNT2002 stands against Pluvicto will not be possible until Novartis details full data from its equivalent study, PSMAfore, possibly at Esmo in October. When it toplined the results Novartis said only that Pluvicto generated a statistically significant improvement in radiographic PFS. Overall survival data, and an FDA submission, are expected later this year.

**Cardiovascular outcomes**

Lastly, investors are still awaiting the results of **Wegovy**'s outcomes trial, Select, in patients with obesity. Previewed already by *Vantage*, Select is powered to show a 17% relative Mace reduction and some analysts have suggested that a 20% improvement over placebo would be a regarded as highly successful.

For **Novo**, a win would provide a massive boost as it tries to maintain Wegovy's lead over Lilly's Mounjaro.

The table below contains a list of upcoming catalysts, with consensus forecasts from *Evaluate Pharma*. Readouts specifically in the fourth quarter are excluded.

| Big biotech's clinical catalysts in Q3/H2 2023 | | | | | |
|---|---|---|---|---|---|
| **Product** | **Company** | **Therapy area** | **Q3 clinical catalyst** | **2028e indication sales ($m)** | **Note/ Vantage coverage** |
| Wegovy | Novo Nordisk | Obesity | Ph3 Select cardiovascular outcomes study, due in the Summer | 9,018* | See text |
| Subcutaneous efgartigimod (Vyvgart) | Argenx | Chronic inflammatory demyelinating polyneuropathy | Ph2 registrational Adhere due July | 1,259 | See text |
| Arikayce | Insmed | Nontuberculous mycobacterial lung disease caused by Mycobacterium avium complex | Confirmatory Arise topline Q3 | 1,201* | Accelerated approval in 2018, second confirmatory study Encore ongoing |
| PNT2002 | Point Biopharma/ Lantheus | Metastatic castration-resistant prostate cancer | Pivotal ph3 Splash H2 | 806 | See text |
| Acoramidis | Bridgebio | ATTR cardiomyopathy | Ph3 Attribute-CM 30-month readout will measure all-cause mortality and cardiovascular hospitalisations in July | 346 | Project missed primary endpoint six-minute walk test, upcoming data readthrough to Alnylam's Onpattro and Amvuttra |
| Verve-101 | Verve | Familial hypercholesterolaemia | First (ex-US) data from ph1 Heart-1 H2 | 315 | PCSK9 base edit, on US clinical hold |
| Paltusotine | Crinetics | Acromegaly | Ph3 Pathfndr-1 Q3 | 307 | Second phase 3, Pathfndr-2, due Q4 |
| Elinzanetant | Bayer (Kandy) | Menopause vasomotor symptoms | Ph3 Oasis-1, -2, -3 H2 | 263 | Inhibits both neurokinin-1 and 3 receptors, Astellas's Veozah, an oral neurokinin-3 receptor, got approved in May |
| Tarlatamab (AMG 757) | Amgen | 3L small cell lung cancer | Ph2 Dellphi-301 H2 | 254 | See text |
| Lumakras + Vectibix | Amgen | 3L colorectal cancer | Ph3 Codebreak-300 H2 | 79 | See text |

**On the market already in different treatment line/indication setting. Sources: Evaluate Pharma, analyst notes & clinicaltrials.gov.*

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