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JP Morgan 2022 roundup – Biogen in focus

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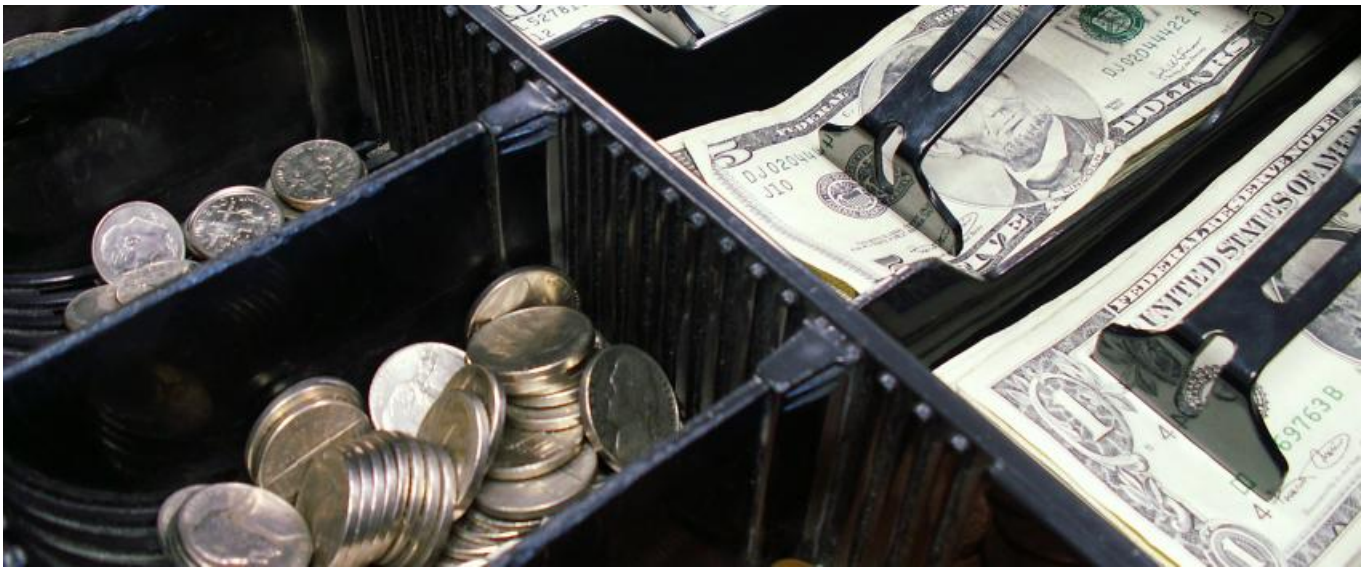

Much of this week's business development might be done and dusted, but for Biogen things are just warming up.

With several companies timing deal announcements to coincide with the start of the JP Morgan healthcare conference yesterday, the meeting looks set to continue with a focus on smaller tie-ups and more subtle updates to development pipelines and filing plans.

Perhaps the biggest spotlight remains on Biogen, which cannot shake the stench of failure from its Alzheimer's drug, Aduhelm, and which will hope for a crucial US healthcare coverage decision, due tomorrow, to kick-start sales; its JP Morgan presentation yesterday gave some clues as to what it expects. Elsewhere, RNA-based therapeutics remain of interest, as does oncology.

Among company presentations taking place late yesterday, **Mirati** quietly revealed that it had filed its Kras G12C inhibitor adagrasib with the FDA at last – some 12 months after its rival sotorasib was filed by Amgen. The latter is, of course, already approved for NSCLC in the US as Lumakras, and got an EU nod (as Lumykras) yesterday.

Despite promise in colorectal cancer, Mirati's filing is also in NSCLC, where the phase 2 portion of the Krystal-1 trial has yielded a 43% overall response rate. A key update to this, including duration-of-response data, will not emerge until the first half of this year, possibly at Asco, and the FDA seems unlikely to rule on the filing until it has seen these.

Mirati told JP Morgan that the update would be "similar to what was presented last year by Amgen". As for colorectal cancer, where on a cross-trial basis adagrasib looks better than Lumakras, Mirati promised "additional clarity on a potential pathway for accelerated approval" within the next six months.

RNA remains hot

For its part, **Amgen** today splashed a discovery deal with Arrakis that, while small, at $75m up front, concerned the hot area of target degradation. Unlike Bristol Myers Squibb's cereblons, however, Amgen and Arrakis aim to identify small molecules that degrade RNA, specifically the RNA that codes for "difficult-to-drug" targets.

RNA was also the subject of a tie-up between **Allogene**, which yesterday revealed the lifting of US clinical hold on its pipeline, and Antion. The goal here is to use microRNAs to silence multiple gene targets and develop a new generation of allogeneic Car-T therapies; terms were not disclosed.

RNA was also in focus recently when Pfizer and Biontech agreed to develop an mRNA-based shingles vaccine that could eventually threaten **Glaxosmithkline's** biggest growth driver, Shingrix.

Glaxo has long faced questions about its strategy, but its chief executive, Emma Walmsley, brushed off concerns about the potential rival today, pointing to Shingrix's 97% efficacy figure, as well as "eight years of sustained protection" – possibly a dig at the fading effect of mRNA-based Covid vaccines.

At JP Morgan yesterday **Pfizer's** chief exec, Albert Bourla, said mRNA vaccines could have a better tolerability profile, with similar efficacy. Of course, this still needs to be proved, and the group plans to start clinical trials of its shingles contender in the second half of this year, or perhaps even sooner.

Coverage decision

But the spotlight was on **Biogen**, which this week expects a vital US national coverage determination (NCD) that will spell out the conditions under which all Medicare contractors will have to provide and pay for its controversial Alzheimer's disease drug Aduhelm.

A draft decision on the NCD is expected tomorrow, and Biogen has already convened an analyst call for Thursday before the markets open. Biogen told JP Morgan yesterday that it would first see the draft at the exact same time as everyone else, and that it had a team waiting for it to be posted.

Aduhelm polemics have centred on its ropey dataset and price, and Biogen last month caved in and halved the drug's wholesale acquisition cost to around $28,000 a year. Its chief executive, Michel Vounatsos, yesterday accepted that the outcry from doctors and patients had proved the initial pricing decision wrong, but characterised the cut as "courageous".

Still, the Centers for Medicare & Medicaid Services "doesn't take price into consideration when they consider the NCD", Alisha Alaimo, president of Biogen US, told JP Morgan. The wide-ranging process includes reviews of clinical data, consultations with professional societies, and external technology assessments.

While potential outcomes range from full Medicare coverage to non-coverage, Evercore ISI analysts expect a decision somewhere between full coverage and coverage with evidence development. Biogen would not speculate on which of the five possible scenarios it expected, but said there would be a 30-day public comment period, with a final NCD posted by April 12, stressing that final determination could look very different from the draft.

The group is advocating for coverage aligned to the clinical trial patient population, and "that is the outcome that we would like to see". Mr Vounatsos, whose reputation is in many ways riding on Aduhelm, said "anything that starts to provide access in [the US] is very good news. It means that the door is open."

Adcom approaches

Meanwhile, in a curtain-raiser to tomorrow's JP Morgan presentation, **Bluebird Bio** revealed that a US adcom had been scheduled for March 9 for Lentiglobin in beta-thalassaemia, before a May 20 Pdufa date. The gene therapy is approved in the EU for this use as Zynteglo, but trials in sickle cell disease are subject to a partial US hold.

Bluebird recently spun its oncology business into a new company, **2Seventy Bio**, which today announced the discontinuation of bb21217, an anti-BCMA Car-T therapy follow-up to Abecma. 2Seventy cited the strength of Abecma's dataset as a reason; bb21217 findings presented at Ash 2020 had suggested marginally better efficacy than Abecma, with meaningfully worse toxicity.

However, yesterday's slew of deals was not enough to lift sentiment around the biotech market; today's updates are unlikely to move the needle either.