Evaluate Vantage

May 11, 2023

2023’s biggest launches: the story so far

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Alzheimer’s has already grabbed attention but plenty of big regulatory decisions still loom for Sarepta, Crispr, Astellas and more.

The sellside expects a bumper year for blockbuster approvals, a recent *Evaluate Vantage* analysis revealed, but which products are creating all the excitement? A handful of significant new agents have already been approved, in Alzheimer’s disease, geographic atrophy and respiratory syncytial virus, and there is no shortage of pending regulatory news for the remainder of the year.

Novel therapies are set to move into sharper focus, with two gene therapies approaching the final stages of regulatory review. Sarepta’s Roche-partnered Duchenne muscular dystrophy therapy faces probing by an FDA panel tomorrow, and it is hard to imagine Crispr’s Vertex-partnered gene edited project avoiding similar scrutiny later in the year.

Biomarin’s haemophilia A gene therapy also awaits the FDA’s final verdict next month. The product is in the process of being launched in Europe.

The table below highlights a selection of other potential blockbuster candidates that could receive regulatory verdicts later this year, according to *Evaluate Pharma*. The chart below, based on 2028 consensus sales forecasts, includes only agents that have not yet been through a review in any major region.

On the cards: 2023's potential blockbuster launches				
Project	**Company**	**Description**	**Global 2028e sales ($bn)**	**Status**
SRP-9001	Sarepta/ Roche	Gene therapy for Duchenne muscular dystrophy	2.8	12 May adcom; 29 May Pdufa date
Donanemab	Lilly	Anti-amyloid beta MAb for Alzheimer's disease	2.1	US filing due June 2023
Datopotamab deruxtecan	Daiichi Sankyo/ Astrazeneca	Trop2-directed ADC for lung, other cancers	2.0	Ph3 data imminent; H1 US filing guided
Fezolinetant	Astellas Pharma	NK-3 receptor antagonist for menopause symptoms	1.9	22 May Pdufa; EMA decision due late 2023
CTX001 (exa-cel)	Crispr/Vertex	CRISPR/Cas9 gene therapy for sickle cell and beta thalassaemia	1.7	BLA filed with FDA, acceptance pending; EMA decision due 2024
Lebrikizumab	Lilly/ Almirall	Anti-IL-13 MAb for atopic dermatitis	1.7	November Pdufa date (estimated) and H2'23 EMA decision
Abrysvo	Pfizer	RSV vaccine	1.3	May Pdufa; H2'23 EMA decision
Epcoritamab	Abbvie/ Genmab	CD20-directed bispecific for B-cell lymphoma	1.2	21 May Pdufa; EMA decision expected late 2023
Zimura	Astellas (Iveric acquisition pending)	Complement C5a/C5b-9 inhibitor for geographic atrophy	1.2	19 August Pdufa
Zuranolone	Biogen/ Sage/ Shionogi	GABA A receptor regulator for depression	1.1	5 August Pdufa
Note: sales are total worldwide including as booked by global partners, where relevant. Source: Evaluate Pharma.				

Delays are always possible, of course, meaning some of the above are likely to become 2024 launch stories. Datopotamab is a likely candidate, considering that the Daiichi and Astrazeneca antibody-drug conjugate has yet to generate pivotal data.

Another Japanese major also faces a big regulatory year. Astellas’s fezolinetant for menopause vasomotor symptoms should receive the FDA’s delayed decision later this month and, assuming that its proposed acquisition of Iveric goes through, it could gain the second product to be approved for geographic atrophy in the US.

Apellis's Syfovre was the first to reach the market in the eye disease, a product that ranks as one of the most notable new arrivals so far this year.

As for other products that have already crossed the line, Eisai’s Leqembi surely ranks as one of the most high profile. Restrictive reimbursement rules in the US are holding back the launch of the Biogen-partnered Alzheimer’s antibody for now.

Should it win approval the same will apply to Lilly’s donanemab, which is due to be filed in the coming months after succeeding in phase 3 last week. Until the reimbursement situation in the US is relaxed, the timeline on which is uncertain, it is tricky to generate a reliable outlook for either of these Alzheimer's products. Longer term, they clearly hold multi-billion dollar potential.

Even outside the Alzheimer's developments, a big year for regulatory approvals seems to be building. This will come as a relief after last year's dip in the FDA's output, and amid the agency's cooling on the accelerated approval pathway.

Launch under way: 2023's biggest arrivals so far			
Product	**Company**	**Description**	**Global 2028e sales ($bn)**
Leqembi	Eisai/ Biogen	Anti-beta amyloid MAb for Alzheimer's	4.7
Syfovre	Apellis Pharmaceuticals	Complement factor C3 inhibitor for geographic atrophy	2.3
Arexvy	GSK	RSV vaccine	1.7
Beyfortus*	Sanofi/ Astrazeneca/ Sobi	RSV MAb	1.7
Altuviiio	Sanofi/ Sobi	Ultra long-acting FVIII therapy for haemophilia A	1.1
**Approved in EU, FDA decision due Q3. Note: sales are total worldwide including as booked by global partners, where relevant. Source: Evaluate Pharma.*			

This story has been amended with the correct Pdufa date for epcoritamab.