Evaluate Vantage

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Go or no go? Decision day looms for Eisai and Biogen

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Leqembi seeks full approval, while Takeda hopes for a dengue green light and Verrica looks to break its streak of bad luck.

In a month where no adcoms feature on the FDA's docket and only a handful of Pdufa and supplementary decisions loom, biopharma watchers could be forgiven for thinking that the agency is getting into holiday mode early.

But what July lacks in approval decisions it makes up for in importance, with a verdict on full approval for Eisai and Biogen's anti-amyloid agent Leqembi a huge milestone for the sector. Other agents up for consideration include Takeda's dengue vaccine Qdenga, which has been given a priority review, while Verrica will be hoping fourth time is the charm.

No surprises

Endorsement from an FDA advisory committee last month has all but guaranteed that Eisai and Biogen will see accelerated approval for its Alzheimer's treatment converted to a full nod. Full approval would help improve clarity around the reimbursement situation, with questions remaining around the registry for patients that CMS has insisted upon.

Evaluate Pharma's sellside consensus has Leqembi sales at around $4.4bn in 2028, a figure that should be more achievable once the drug is prescribed outside of clinical trial settings, which should be allowed following full approval. However, concerns remain about Aria, the brain swelling disorder associated with anti-amyloid MAbs.

Not again

Three knockbacks in two years is quite the sting. Executives at Verrica, however, will be keen to point out that most of their FDA rejections for Ycanth, a treatment for the viral skin condition molluscum contagiosum, have been down to manufacturing, not safety or efficacy. Two rejections were due to deficiencies at the same contract manufacturing organisation.

At present there are no approved treatments for molluscum contagiosum. This unmet need, and the fact Verrica has shifted production of Ycanth, a formulation of cantharidin, should improve the product's chances of approval. With a $32.5m raise completed in February Verrica says it has enough cash to support the launch of Ycanth, as well as general operations into the first quarter of 2024.

Astrazeneca and Sanofi’s RSV contender

In June an FDA committee unanimously voted to approve Astrazeneca and Sanofi’s jointly-developed RSV antibody Beyfortus, which is already approved in Europe. US approval would make Beyfortus the first single-shot product to be used in both babies and toddlers in the country.

High expectations exist, with sellside sales forecasts sitting at $1.7bn in 2028. However, should an RSV vaccine for pregnant women from Pfizer take off, longer term demand could wane. That vaccine, approved in elderly people as Abrysvo, could be approved for maternal use later this year.

The tables below list first-time and supplementary US approval decisions due next month, with consensus forecasts from *Evaluate Pharma*.

Notable first-time US approval decisions due in July 2023					
Project	**Company**	**Pdufa date**	**Indication(s)**	**2028e SBI ($m)**	**Note**
Ycanth (VP-102)	Verrica	23 July (resubmitted)	Molluscum contagiosum	212	See text
Quizartinib (Vanflyta) + standard cytarabine and anthracycline induction	Daiichi Sankyo	24 July	Newly diagnosed FLT3-ITD +ve AML	116	Delayed from April owing to REMs
Risvan (Doria/ risperidone ISM)	Laboratorios Farmacéuticos ROVI	27 July	Schizophrenia	-	Previous CRL owing to manufacturing inspection
I/Ontak (E7777)	Citius Pharmaceuticals	28 July	Cutaneous persistent or recurrent T-cell lymphoma	195	Reformulation of denileukin diftitox (Ontak), which was withdrawn due to production issues; Citius plans to spin off I/Ontak into a standalone company
Qdenga (TAK-003)	Takeda	July? (filed Nov 2022, given priority review)	Dengue vaccine (4-60 years of age)	922	Approved in Europe
Beyfortus (nirsevimab)	Astrazeneca/ Sanofi/Sobi	Q3	Prevent RSV lower respiratory tract disease in neonates and infants	1,727	See text
AT-GAA (Pombiliti)	Amicus	Q3	Adults with late-onset Pompe disease	443	Previous inspection delays
Tuoyi (toripalimab)	Coherus	Q3	Nasopharyngeal carcinoma	317*	Previous inspection delays
Bimzelx	UCB	Q3 (resubmission)	Plaque psoriasis	937	Delayed from Q2 to Q3, previous CRL due to pre-approval inspections
Etrasimod	Pfizer	H2	Ulcerative colitis	859	S1P inhibitor, competitor to Bristol's Zeposia (*Pfizer seeks to put etrasimod first*)
**Sales by indication not split out. Sources: Evaluate Pharma & company releases.*					

Supplementary and other notable approval decisions due in July 2023			
Product	**Company**	**Indication (clinical trial)**	**Date**
Leqembi	Eisai/Biogen	Alzheimer's disease (full approval, Clarity-AD)	6 July (positive adcom in June)
Cosentyx	Novartis	Hidradenitis suppurativa (Sunshine, Sunrise)	H2
Intravenous Cosentyx	Novartis	Adult patients with psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondyloarthritis (Invigorate 1, Invigorate 2)	H2
Sources: Evaluate Pharma & company releases.			