Evaluate Vantage

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Upcoming events: April 22–28

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Welcome to your weekly digest of approaching regulatory and clinical readouts.

All information is sourced to analyst notes and the *EvaluatePharma Calendar of Events* tool.

Committee for Medicinal Products for Human Use meeting April 22-25:

The April CHMP meeting is taking place next week, and the following projects await European decisions expected in Q2 that could be made at the meeting.

Outcomes are expected on April 26 and will be posted on the EMA website.

Bayer/Onyx Pharmaceuticals: Stivarga

The CHMP decision on Stivarga (regorafenib) in metastatic colorectal cancer (mCRC) is expected soon. Leerink Swann analysts note that in the US the drug had a strong initial launch in mCRC at the end of last year, with Bayer recording $41m in 2012 sales. Onyx receives a 20% royalty.

The drug, which shares its mechanism of action with the companies' blockbuster Nexavar, was also approved in the US in February this year in the smaller indication of gastrointestinal stromal tumor (GIST).

According to *EvaluatePharma* forecasts, Stivarga's 2018 worldwide sales are expected to reach $517m in mCRC and $77m in GIST. The drug has an NPV equivalent to 2% and 6% of Bayer and Onyx's market caps respectively. Global expansion continues with the recent approval in Japan in mCRC, while GIST approval is expected there towards the end of the year.

Johnson & Johnson: Invokana

Johnson & Johnson's Invokana, known generically as canagliflozin, became the first SGLT2 inhibitor to reach the US type 2 diabetes market with approval at the end of March, and now the European decision looms.

The road to approval for the SGLT2 class has not been a smooth one, and risks of genitourinary infections have been well documented (*Adcom backing gives canagliflozin a chance at an open diabetes field, January 11, 2013*).

Invokana's closest competitor is Forxiga (dapagliflozin), an SGLT2 inhibitor from Bristol-Myers Squibb and AstraZeneca that was approved in Europe last November. However, Forxiga's prospects in the US were scuppered by a cancer signal, with Wells Fargo analysts expecting it to be refiled mid-2013 (*Event – J&J hopes canagliflozin flourishes where Forxiga failed, January 4, 2013*).

According to *EvaluatePharma* worldwide sales of Invokana will reach $810m by 2018. Forxiga sales are not far behind at $760m.

Sanofi/Bayer/BTG: Lemtrada

The CHMP decision on the relapsing multiple sclerosis project Lemtrada is expected shortly. The monoclonal antibody suffered a delay in the US when the companies were issued with a refuse to file letter last August, with the regulator requesting that they modify the presentation of datasets. No new studies were required (*Lemtrada knock-back rebounds onto BTG, August 29, 2012*). A PDUFA is expected in the second half of the year.

EvaluatePharma's worldwide sales forecasts are $437m for 2018; however, this falls well short of the $3.8bn for the recently approved Tecfidera (BG-12), the oral MS drug from Biogen Idec. Tecfidera was approved in the US and received a positive CHMP opinion as a first-line treatment (*Tecfidera hits the ground running with FDA thumbs up, March 28, 2013*).

According to analysts at Cannacord, by 2018 Tecifidera will have gained 21.2% of the European market share, with Biogen's Tysabri taking 14.7%. Lemtrada will have a tough time, with just a 5.4% share.

European Association for the Study of the Liver meeting:

The EASL conference is taking place April 24-28 in Amsterdam, the Netherlands. Late breaker abstracts are to be released on April 23 and data are expected from sofosbuvir (Gilead), daclatasvir (Bristol-Myers Squibb) and alisporivir (Novartis).

Watch out for *EP Vantage's* detailed analysis next week.

2013 Bio International Convention:

Bio will take place April 22-25 in Chicago, Illinois. A report on the orphan drug market will be released on April 23 by *Evaluate* with commentary from *EP Vantage*. Please see the press release for full details.

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