From: Debra Barrett [/O=TEVA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DBARRETT]
Sent: 2/21/2016 12:14:33 PM
To: Rob Falb [rob.falb@tevapharm.com]
CC: Grant Erdel [grant.erdel@tevapharm.com]
Subject: Re: BioCentury Extra for Friday, February 19, 2016 [MARKETING]

Agreed on plan B. I responded to him yesterday but Rick Malamut asked that he be included in everything. Grant - yesterday I emailed Michael and Jim and said that we need final sign off to approach the FDA as we need to do a letter or whatever and we need to know that we can say Erez and Michael. Not sure why but haven't heard back yet. The problem is when I finally see them they will be in a crazed rush to get it done... So it's hurry up and wait

Sent from my iPhone

On Feb 21, 2016, at 11:40 AM, Rob Falb <Rob.Falb@tevapharm.com> wrote:

Sorry. Thought I responded. Different parts of the brand team should have the info and I will work on getting it all consolidated.

In thinking about this issue I am struck by the similarities to the Plan B One Step approval being reversed by HHS. In both cases the merits of the product were secondary to the surrounding politics.

On Feb 21, 2016, at 11:25 AM, Debra Barrett <Debra.Barrett@tevapharm.com> wrote:

Falbie - did you get this?

Sent from my iPhone

On Feb 20, 2016, at 1:48 PM, Debra Barrett <Debra.Barrett@tevapharm.com> wrote:

Falbie - if we go ahead and try to get an Erez/Hayden level call w Califf/Woodcock and then maybe Hill outreach when the ad comm is public, I think we need a document w the basic facts about Vantrella, high level the data we submitted, how long the delay has been, how we expect Vantrella to penetrate the market, how much of a problem the abuse is so that further delay would cost this much. If Grant agrees, I think you should work w the Vantrella team to pull that together swap so we have it ready to go. Thoughts?

Sent from my iPhone

On Feb 20, 2016, at 1:08 PM, Rob Falb <Rob.Falb@tevapharm.com> wrote:

Deb -- you are correct about the FDA's latest strategy regarding ad comms for non-ADT opioids. My guess is that in the case of Vantrela ER FDA is reacting to Senator Markey who has put a hold on the Califf nomination for several reasons, including his upset that the agency did not convene ad comms for any of the already approved ADT products. He wants guaranteed ad comms for ADT products as well.

On Feb 20, 2016, at 11:24 AM, Debra Barrett <Debra.Barrett@tevapharm.com> wrote:

You know the plan requires ad comms for non AD opioids but I don't think it requires for AD opioids. Rob - am I right about that?

Sent from my iPhone

On Feb 20, 2016, at 10:00 AM, Grant Erdel <Grant.Erdel@tevapharm.com> wrote:

Yeah it's looking good at this point for cloture.

Sent from my iPhone

On Feb 20, 2016, at 8:26 AM, Debra Barrett <Debra.Barrett@tevapharm.com> wrote:

We expect Califf to have the 60 votes in spite of Markey hold right?

Sent from my iPhone

Begin forwarded message:

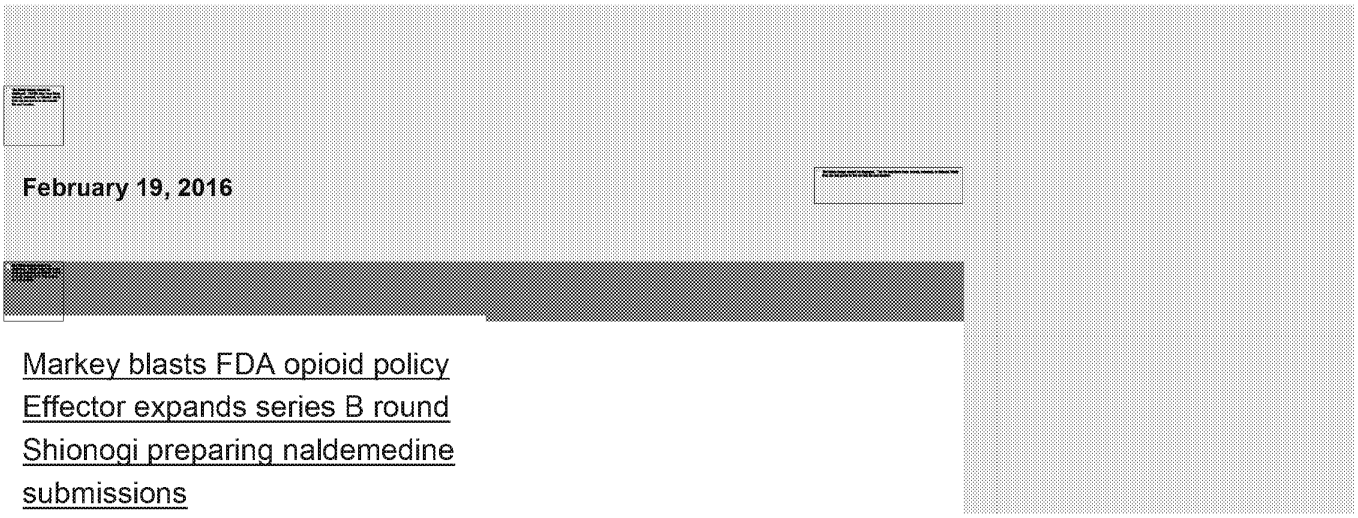
From: Michael Hayden <Michael.Hayden@teva.co.il>
Date: February 20, 2016 at 4:04:43 AM EST
To: Erez Vigodman <Erez.Vigodman@teva.co.il>
Subject: Fwd: BioCentury Extra for Friday, February 19, 2016 [MARKETING]

See issue around committees on abuse deterrent opioids .
M

Sent from my iPhone

Begin forwarded message:

From: "BioCentury Extra (External)" <biocentury_extra@biocentury.com>
Date: 20 February 2016 at 03:22:17 GMT+2
To: Michael Hayden <Michael.Hayden@teva.co.il>
Subject: BioCentury Extra for Friday, February 19, 2016 [MARKETING]
Reply-To: "biocentury_extra@biocentury.com" <biocentury_extra@biocentury.com>



FDA approves UCB's epilepsy drug Briviact
AZ's gout drug Zurampic gains EU approval
FDA accepts NDA for Spectrum's EOquin
Management tracks CMS takes small steps to cut Medicare drug costs
Stakeholders shaping FDA plan for patient perspectives

Markey blasts FDA opioid policy

U.S. Sen. Edward Markey (D-Mass.) said he would continue to oppose Robert Califf's nomination for FDA commissioner unless FDA agrees to hold advisory committee meetings for all opioid candidates. In a letter to HHS Secretary Sylvia Burwell, Markey said he was disappointed that FDA's new Opioids Action Plan "inexplicably" commits the agency to hold committee reviews only of non-abuse-deterrent opioids (see BioCentury Extra, Feb. 4).

Markey released an analysis showing that FDA held advisory committee meetings for only four of 11 abuse-deterrent opioids approved since 2010, and said the new plan would represent the status quo.

Markey has placed a hold on Califf's nomination, citing concerns about how FDA approves and regulates opioids (see BioCentury, Feb. 1).

Senate Majority Leader Mitch McConnell (R-Ky.) has scheduled a vote for Monday, Feb. 22, on a cloture motion that would cut off debate on Califf's confirmation. If at least 60 Senators vote for the motion, Califf could be confirmed despite the holds (see BioCentury Extra, Feb. 11). Back to top

Effector expands series B round

Effector Therapeutics Inc. (San Diego, Calif.) raised an additional $16 million in series B funding, bringing the round's total to $56 million. The new funds came from new investor Sectoral Asset Management, as well as existing investors. Effector said in December it raised $40 million from investors including Altitude Life

BioCentury, Jan. 4).
Effector's lead compound, eFT508, is in a U.S. Phase I/II trial to treat advanced solid tumors. This half, the company plans to submit an IND for eFT508 in lymphoma.
eFT508 is an inhibitor of MAP kinase interacting serine-threonine kinase 1 (MKNK1; MNK1) and MKNK2 that blocks multiple processes in tumors by inhibiting protein translation upstream of eukaryotic translation initiation factor 4E (eIF4E).
Sectoral's Maha Katabi joined Effector's board. Back to top

Shionogi preparing naldemedine submissions

Shionogi & Co. Ltd. (Tokyo:4507) is on track to submit regulatory applications this quarter in the U.S. and Japan for naldemedine (S-297995) to treat opioid-induced constipation (OIC), spokesperson Lisa Ellen told BioCentury. The company presented data Friday at the American Academy of Pain Medicine from COMPOSE I, one of three Phase III studies in which naldemedine met the primary endpoint.
Shionogi said naldemedine increased the frequency of spontaneous bowel movements (SBM) from baseline for at least nine of 12 weeks on treatment in 47.6% of patients vs. 34.6% for placebo, meeting the endpoint. Abdominal pain occurred in 6.3% of patients receiving naldemedine vs. 1.8% for placebo, while 6.6% of naldemedine-treated patients and 2.9% receiving placebo reported diarrhea. Both adverse events were treatment related.
Last year, Shionogi said naldemedine met the primary endpoints in the Phase III COMPOSE II and COMPOSE IV studies.
Naldemedine is an oral peripheral mu opioid receptor antagonist. Back to top

FDA approves UCB's epilepsy drug Briviact

FDA approved Briviact brivaracetam from UCB Group (Euronext:UCB) as an adjunct therapy to treat partial-onset seizures in epileptic patients aged 16 and older. UCB plans to launch Briviact after the U.S. Drug Enforcement Administration schedules the drug, which the company expects to occur within 90 days. UCB

FDA required that Briviact be dispensed with a medication guide detailing its risks, which UCB said include suicidal behavior and ideation, neurological and psychiatric adverse reactions and hypersensitivity.
Last month, the European Commission approved Briviact for the same indication. UCB has launched the high affinity synaptic vesicle protein (SV2A) ligand in the U.K. and Germany (see BioCentury Extra, Jan. 20). Back to top

AZ's gout drug Zurampic gains EU approval

The European Commission approved an MAA for Zurampic lesinurad from AstraZeneca plc (LSE:AZN; NYSE:AZN) in combination with a xanthine oxidase inhibitor (XOI) to treat hyperuricemia in adults with gout. The company said it will conduct a postapproval cardiovascular safety study and a renal efficacy and safety study of the drug.
FDA approved Zurampic in December, and required a postmarketing renal and CV study. The drug's U.S. label has a boxed warning noting risk of renal failure (see BioCentury Extra, Dec. 22, 2015).
Zurampic is a selective solute carrier family 22 organic anion urate transporter member 12 (SLC22A12; URAT1) inhibitor. AZ gained the drug via its acquisition of Ardea Biosciences Inc. in 2012. Back to top

FDA accepts NDA for Spectrum's EOquin

Spectrum Pharmaceuticals Inc. (NASDAQ:SPPI) said FDA accepted for filing an NDA for EOquin apaziquone to treat non-muscle invasive bladder cancer (NMIBC). Its PDUFA date is Dec. 11.
The company said FDA plans to hold an advisory committee meeting to discuss EOquin, an analog of mitomycin C that is reduced by intracellular reductases into active DNA-damaging moieties.
Spectrum gained $0.23 to $4.68 on Friday. Back to top

Management tracks

Metabolic play MannKind Corp. (NASDAQ:MNKD; Tel Aviv:MNKD) said Alfred Mann resigned as executive chairman. The board named Lead Director Kent Kresa chairman. Mann will be chairman emeritus and will continue to advise the company.
Gastrointestinal company Protagonist Therapeutics Inc. (Milpitas, Calif.) named Thomas O'Neil CFO. O'Neil was CFO at Arcadia Biosciences Inc. (NASDAQ:RKDA).
Protein degradation play C4 Therapeutics Inc. (Cambridge, Mass.) named Thomas Needham CBO. He was a managing director at Synthesis Capital.
Cancer company Sunesis Pharmaceuticals Inc. (NASDAQ:SNSS) promoted Deborah Thomas to SVP of regulatory affairs, quality assurance and non-clinical development from VP of regulatory affairs and medical writing.
Regenerative medicine play TissueGene Inc. (Rockville, Md.) named Gurdyal Kalsi

for clinical development and medical affairs at Emergent BioSolutions Inc. (NYSE:EBS).
Immunotherapy company Atreca Inc. (Redwood City, Calif.) named Susan Berland EVP and CFO. She was CFO at Mendel Biotechnology Inc. (Hayward, Calif.). Back to top

CMS takes small steps to cut Medicare drug costs

CMS proposed updates to Medicare Advantage and Part D programs, including measures to limit drug spending in Part D plans and to curtail opioid abuse. The center issued the proposals Friday in a draft of its annual call letter.
CMS would allow Part D plans to limit beneficiaries to a one-month supply of designated drugs, which the center said would eliminate waste from patients who discontinue treatment or change dosage. CMS also would encourage sponsors to inform patients when new drugs are added to formularies mid-year, and to direct beneficiaries to the Medicare Drug Spending Dashboard from the Medicare Plan Finder website to raise awareness of drug costs.
The center also proposed changes aimed at preventing opioid abuse, suggesting edits to Part D plans that would prevent opioid overutilization at the point of sale.
Comments on the draft are due March 4. Back to top

Stakeholders shaping FDA plan for patient perspectives

FDA said Friday it is developing a comprehensive plan for integrating patient perspectives into medical product development. The plan will be informed by comments collected in fall 2014 as part of its patient-focused drug development initiative. The agency released its summary of the comments on Friday.
The comments, from trade organizations, individual patients and patient advocacy groups, recommended that FDA create a centralized FDA office to advise on and implement patient engagement activities or establish an external advisory board to guide patient participation in regulatory processes.
The agency said multiple commenters called for the creation of a new mechanism for interacting with drug sponsors, or new guidance on interactions between patients and manufacturers, particularly at early development stages. Stakeholders also requested transparency from the agency on how patient input is used as products are evaluated.
FDA also highlighted comments suggesting that it collaborate with patient advocates to create public-private partnerships to develop protocols for obtaining patient perspectives.

agreements to reauthorize drug and device user fees that Congress is slated to ratify in 2017 (see BioCentury, Sept. 7, 2015). Back to top

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