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Financings Roundup

IPO News Still Flowing: Pacific Biosciences Files for $200M

By Jennifer Boggs
Assistant Managing Editor

The late summer burst of IPO activity continued as sequencing specialist Pacific Biosciences Inc. took aim at the public markets, hoping to raise $200 million ahead of a planned 2011 commercial launch for third-generation sequencer PacBio RS.

Following a spring flurry of initial public offering pricings from the likes of Anthera Pharmaceuticals Inc., AVEO Pharmaceuticals Inc., Tengion Inc. and Alimera Sciences Inc., U.S. IPO activity quieted over the past few months, leading to worries that the window, cracked open late last year by specialty pharma firm Cumberland Pharmaceuticals Inc., might again be sliding shut. But August kicked off with a much-awaited pricing by Trius Therapeutics Inc., followed by another pricing by NuPathe Inc. and proposed IPO filings

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HRA's Five-day Emergency Contraceptive Wins FDA OK

By Donna Young
Washington Editor

WASHINGTON – The FDA Friday approved HRA Pharma SA's emergency contraceptive pill ella (ulipristal), which can be taken up to five days after unprotected intercourse or a known or suspected contraceptive failure.

The drug, a selective progesterone receptor modulator, has been marketed as an emergency contraceptive in Europe since last fall under the brand name ellaOne.

Paris-based HRA Pharma's partner in Europe, PregLem SA, also is developing ulipristal as a treatment for uterine fibroids under the trade name Esmya. Geneva-based PregLem in May said the drug met its endpoints in the first of two Phase III studies, with an expected approval in uterine fibroids by the end of the year if the second study is equally successful. (See *BioWorld Today*, May 19, 2010.)

HRA Pharma's pill provides women with a longer

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Lung Cancer Kicks the EGFR Habit

Inflammation Cause of Primary, Secondary Erlotinib Resistance

By Anette Breindl
Science Editor

Resistance to targeted therapies often comes in the form of additional mutations. But according to a new report, resistance to at least one targeted therapy can also come about through a different path. High levels of inflammation can lead cells to turn on a gene expression program that allows cancer cells to become resistant to Tarceva not through mutations in its target – the epidermal growth factor receptor tyrosine kinase or EGFR – itself, but through changes in the microenvironment.

"Resistance can arise not only through secondary mutations in EGFR, but also through a parallel pathway," Raffaella Sordella told *BioWorld Today*. Sordella is at Cold Spring Harbor Laboratories and the senior author of the study, which appears in the Aug. 16, 2010, online edition of

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NewCo News

Del Mar Pharma Bets on Glioblastoma Salvage Therapy

By Catherine Shaffer
***BioWorld Today* Contributing Writer**

Founder-funded Del Mar Pharmaceuticals is developing a treatment for a group of cancer patients that doesn't typically get a lot of attention from the industry – those who have failed front-line biologic therapies like Avastin (bevacizumab).

The objective is glioblastoma, a rare and aggressive cancer of the brain. Founders Jeff Bacha, Dennis Brown and William J. Garner used a bioinformatics-based approach to identify a compound that had the clinical and safety characteristics they needed.

Del Mar is now preparing an IND for its lead candidate VAL083. The compound has a clinical history overseas, and

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Del Mar

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some older studies indicated efficacy against glioblastoma.

Avastin was not yet available at the time, so those studies are not specific to a patient population that has failed Avastin. "Twenty years ago, when this work was originally done, those patients obviously didn't exist because Avastin was just approved in the indication about a year ago," Bacha told *BioWorld Today*.

There are few end-stage or salvage therapies available for glioblastoma. Bacha said that "the competition is not as fierce as it is in some other areas" because companies tend to focus on front-line therapy rather than end-stage or salvage therapy.

VAL083 could potentially be administered in combination with another therapy.

Bacha cites antibodies and vaccines currently in development as potential partners for the compound. "Particularly in glioblastoma and some of the other cancers, these patients currently have no options other than experimental or palliative care."

Bacha called VAL083 a "very de-risked asset" because it has been studied previously in a number of National Cancer Institute-supported studies. "There are over three dozen published Phase II clinical trials utilizing the compound in a number of different indications," Bacha added.

VAL083 is commercially available overseas, but was never approved nor brought forward beyond Phase II in North America, according to Bacha. Del Mar has not disclosed the identity of the compound or its overseas manufacturer, but calls VAL083 an "alkylating agent."

Bacha compares VAL083 to Treanda (bendamustine, Cephalon Inc.) and Omapro (omacetaxine, ChemGenex Pharmaceuticals Ltd.).

Treanda was developed by Salmedix Inc. for treatment of non-Hodgkin's lymphoma (NHL) that is refractory to Rituxan (rituximab, Genentech and Biogen Idec Inc.). Treanda received orphan drug status in 2005 and was given fast-track status by the FDA in 2008.

Treanda's sales growth reached $222.1 million in 2009, and Del Mar predicts that its annual peak sales could be $500 million. (See *BioWorld Today*, March 31, 2010.)

Omapro was developed by ChemGenex for chronic myeloid leukemia (CML) that is refractory to Gleevec (imatinib, Novartis AG). Omapro received fast-track status from the FDA in 2006, and orphan drug status from the FDA in 2009. ChemGenex has filed a new drug application for patients who failed Gleevec and also had a mutation known as T315I. (See *BioWorld Today*, July 15, 2010.)

If it can match the success of Treanda or Omapro with VAL083, Del Mar estimates an annual market opportunity of more than $200 million, based on Avastin pricing and failure rates. Avastin is considered one of the most expensive of all drugs.

Del Mar's business plan is to commercialize VAL083 for post-biologic failure in orphan drug indications. Orphan drug status enables a much higher price point and seven years of market exclusivity. The company has identified a second indication for VAL083 and will expand its IND to include that "probably toward the end of the year," Bacha said.

Thus far, the founders have been able to move to the IND stage using "internal resources," Bacha said. It will soon undergo a formal institutional financing to bring in more funding and more individuals to participate in the company.

Del Mar is oriented toward acquisition within 12-18 months, but is open to going public, as well.

"We are certainly not afraid to test the public markets. We do have what we feel is a later-stage asset that is well de-risked that also has a streamlined development pathway in terms of the regulatory pathway that we'll follow and a very, very experienced team to make it happen," Bacha said.

Del Mar is named after a California city that Bacha once lived in. Because it means "the sea" in Spanish, he also liked the resonance with the concept of reaching out or bridging the ocean, because the company will be commercializing technology developed overseas. ■