



## A.P. Pharma Receives FDA Complete Response Letter for APF530

March 28, 2013

*- Company Revises Projected Launch Timing from 2H 2013 to 1H 2014 -*

*- Conference Call to Be Held at 8:30 a.m. Eastern Time -*

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Mar. 28, 2013-- A.P. Pharma, Inc. (OTCBB: APPA.OB), a specialty pharmaceutical company, today announced that it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for its lead product candidate, APF530, for the prevention of chemotherapy-induced nausea and vomiting (CINV). The CRL describes the following issues that must be addressed.

- With respect to chemistry, manufacturing and controls (CMC), the FDA has requested the refinement of one product quality analytical test method, and that certain deficiencies identified during facility pre-approval inspections be addressed.
- The FDA has requested that a human factors validation study evaluating the usability of the APF530 syringe system together with its proposed product labeling and instructions for use be conducted with product assembled using a validated, commercial process.
- With respect to clinical, the FDA has requested a re-analysis of the existing Phase 3 clinical data that reclassifies patients into those receiving moderately emetogenic chemotherapy (MEC) and highly emetogenic chemotherapy (HEC) according to the recently modified ASCO 2011 Guideline. The FDA did not request any new clinical studies.

"We appreciate the FDA's thorough review of the APF530 NDA," stated John B. Whelan, A.P. Pharma's president and chief executive officer. "While disappointed in today's notification, we believe that the issues raised in the CRL are addressable, and we remain firmly committed to the successful development of APF530, which we believe will fulfill an important unmet need and improve the lives of patients suffering from CINV. In order to allow us time to carefully address the issues raised in the CRL, we are now projecting product launch for the first half of 2014, versus our prior guidance of the second half of 2013."

### Conference Call Details

A.P. Pharma will host a conference call on Thursday, March 28, 2013 at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time). Interested investors may participate in the conference call by dialing (877) 856-1964 (domestic) or (719) 386-0001 (international) and use participant code 135738. In addition, the live conference call is being webcast and can be accessed on the "Calendar of Events" page of the "Investors" section of the Company's website at [www.appharma.com](http://www.appharma.com). A replay of the webcast will be posted to this same section of the website available approximately two hours after the call.

### About APF530

A.P. Pharma's lead product, APF530, is being developed for the prevention of both acute- and delayed-onset chemotherapy-induced nausea and vomiting (CINV). One of the most debilitating side effects of cancer chemotherapy, CINV is a leading cause of premature discontinuation of treatment. There is only one injectable 5-HT<sub>3</sub> antagonist approved for the prevention of delayed-onset CINV, so this indication represents an area of particular unmet medical need. APF530 contains the 5-HT<sub>3</sub> antagonist granisetron formulated in the Company's proprietary Biochronomer™ drug delivery system, which allows therapeutic drug levels to be maintained for five days with a single subcutaneous injection. Currently available intravenous and oral formulations of granisetron are approved only for the prevention of acute-onset CINV. Granisetron was selected for APF530 because it is widely prescribed by physicians based on a well-established record of safety and efficacy.

### About A.P. Pharma

A.P. Pharma is a specialty pharmaceutical company developing products using its proprietary Biochronomer™ polymer-based drug delivery platform. This drug delivery platform is designed to improve the therapeutic profile of injectable pharmaceuticals by converting them from products that must be injected once or twice per day to products that need to be injected only once every one or two weeks. The Company's lead product, APF530, is being developed for the prevention of both acute- and delayed-onset chemotherapy-induced nausea and vomiting. A.P. Pharma resubmitted its New Drug Application (NDA) for APF530 to the U.S. Food and Drug Administration (FDA) in September 2012 and received a Complete Response Letter in March 2013. For further information, please visit the Company's web site at [www.appharma.com](http://www.appharma.com).

### Forward-looking Statements

This news release contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve risks and uncertainties, including uncertainties associated with the potential approval of APF530 and the potential timing for such

approval, if approved at all, the projected timing for the commercial launch of APF530, if approved, as well as risks relating to capital resources and liquidity, satisfactory completion of clinical studies, progress in research and development programs, successful launch and acceptance of new products and other risks and uncertainties identified in the Company's filings with the Securities and Exchange Commission. We caution investors that forward-looking statements reflect our analysis only on their stated date. We do not intend to update them except as required by law.

Source: A.P. Pharma, Inc.

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