



December 20, 2017

Dr. Antonio Francesco Di Naro
Chairman and President
ADIENNE Pharma & Biotech
Via Zurigo, 46
6900 Lugano -SWITZERLAND

Dear Dr. Francesco Di Naro:

The U.S. Food and Drug Administration (FDA) is pleased to announce that ADIENNE Pharma & Biotech has been selected to receive a Drug Shortage Assistance Award for its role in preventing or alleviating drug shortages.

ADIENNE is being recognized for its efforts related to the shortage of thiotepa injection, including submitting and obtaining approval of a new drug application for TEPADINA (thiotepa) for injection.

FDA established this award program to recognize companies for making a substantial contribution to preventing or alleviating a drug shortage. FDA hopes this award serves as an incentive for other companies to assist in addressing drug shortages, as ADIENNE has.

FDA intends for the award program to bring attention to manufacturers or companies that assist in addressing a drug shortage and prioritize quality manufacturing, a key component of the Strategic Plan for Preventing and Mitigating Drug Shortages. More information on the strategic plan is on FDA's drug shortages web page (<http://www.fda.gov/drugs/drugsafety/drugshortages/default.htm>).

FDA thanks ADIENNE for working to alleviate the shortage of thiotepa injection. The enclosed press release/web statement template can assist you in publicizing your award.

Sincerely,

Douglas C. Throckmorton, M.D.
Deputy Center Director for Regulatory Programs
FDA, Center for Drug Evaluation and Research

Enclosures:

Certificate

Optional Press Release/Web Statement Template

U.S. Food & Drug Administration
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www.fda.gov