



Vibativ[®], Acetadote[®], Caldolor[®] and Methotrexate Update

August 2019

Earlier this year, we announced a strategic review following our accelerated business development activities, that led to a series of transactions. Because of that progress, we took a fresh look at our portfolio, partners and organization to ensure we have the proper focus and capabilities going forward. Below is a summary of our findings and decisions:

- **Vibativ[®]:** We finalized distribution agreements with *Hikma Pharmaceuticals LLC* for the Middle East, *R. Pharma LLC* for Russia and *Dr. Reddy's Laboratories Ltd* for India. We look forward to seeing these partnerships expand the availability for this potentially life-saving antibiotic to patients in their countries.
- **Acetadote[®] and Caldolor[®]:** *Hong Kong's WinHealth Pharmaceuticals* is assuming responsibility for these brands in China, as we [announced in May](#). Furthermore, we have formed a Strategic Alliance with WinHealth to explore further business opportunities that will advance the mission and goals of both of our organizations.
- **Methotrexate products:** During the second quarter we provided the FDA with additional data to support approval of our new line of methotrexate products, which is designed for the treatment of patients with arthritis and psoriasis. The FDA has provided an expected decision date for September 2019, and we will provide further updates as they become available.

In addition, we decided to return the U.S. rights to *Ethyol[®]* and *Totect[®]* and will focus our hospital efforts on our three key acute care brands – *Caldolor[®]*, *Vibativ[®]* and *Vaprisol[®]*. In order to support this acute care business, we have completed the expansion of our hospital sales division as well as our field-based medical science team.

Meanwhile, we completed enrollment in our study of *Caldolor[®]* in newborns. Once the data gathering and evaluation is complete, we will provide top line results from this trial. We also submitted a label update to the FDA for *Caldolor[®]*. Aiming to further expand the product's label, we provided important data generated from our clinical studies regarding an optimal infusion time, additional safety information as well as geriatric and pediatric administration.

We remain focused on our mission to advance patient care through the delivery of high-quality pharmaceutical products.