e5 Pharma Launches First FDA Approved Generic for Proglycem®

BOCA RATON, FL, December 20, 2019 - e5 Pharma, LLC., today announced the U.S. launch of Diazoxide, USP Oral Suspension, the first generic version of the reference listed drug, Proglycem®. e5 Pharma received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) using the Competitive Generic Therapy (CGT) Pathway.

Created under the FDA Reauthorization Act of 2017 (FDARA), the CGT pathway established a process through which FDA may, at the request of an applicant, designate a drug with "inadequate drug competition" as a CGT and may also expedite the development and review of the abbreviated new drug application (ANDA) for that drug. The pathway also includes a new type of 180-day exclusivity for the first approved applicant of a drug with a CGT designation for which there were no unexpired patents or exclusivities listed in the Orange Book at the time of the original submission of the ANDA.

Chief Executive Officer of e5 Pharma, Bob Edwards, commented, "We are excited to launch our first generic drug designated as a competitive generic therapy. Our mission is to provide patient access to affordable medicine. We are not looking for the next big thing; we are looking for the next great thing. Products that make all the difference in the world to people who need them, regardless of market size."

About e5 Pharma, LLC
e5 Pharma is a specialty pharmaceutical committed to the development and distribution of generic drugs. The company was founded on a single principle that, most times, the simplest solution is also the best solution. Our focus is not necessarily on the development of new molecules, but instead on cost-reducing generic therapies and solutions.