Novugen Secures NCE-1 First-to-File Status
& Achieves Successful Resolution for Pitolisant in the U.S.

We are pleased to announce that on 31st October 2024, Novugen achieved a successful resolution for Pitolisant 4.45 mg and 17.8 mg oral tablets in the U.S.

This achievement for Pitolisant secures NCE-1 (New Chemical Entity) First-to-File (FTF) status and a favorable settlement, positioning Novugen to benefit from six months of shared exclusivity as one of the first suppliers to market. Should its ANDA be approved by the USFDA, we believe that Novugen will be eligible for 180 days of generic marketing exclusivity in the U.S. allowing Novugen to launch on Day 1 alongside one or more NCE-1 filers.

Pitolisant, a Central Nervous System therapy, is primarily indicated for the treatment of Excessive Daytime Sleepiness (EDS) and cataplexy in adults with narcolepsy, along with other related symptoms. This milestone reinforces Novugen's role as a trusted partner in the U.S. pharmaceutical market and amplifies the value we deliver to patients not only in the U.S., but also across every corner of the globe.