SUMMARY OF PEDIATRIC CLINICAL EXPERIENCE WITH NEXOBRID (063)

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Introduction: Early eschar removal is a cornerstone of burn care. Excisional debridement followed by autografting is the preferred standard of care (SOC) but is associated with extensive surgery and potential complications. Phase II clinical trial data with Nexobrid (NXB), a Bromelain derived enzymatic debriding agent for burns, also known as Debrase or Debriding Gel Dressing, has shown increased efficacy in the pediatric subgroup population. The aim of this review is to summarize the clinical trials' results regarding the efficacy of NXB as a debriding agent and its impact on the surgical burden, long-term cosmesis and function in the pediatric subpopulation.

Methods: Seventy-seven children under the age of 18 suffering from deep partial thickness (DPT) to full thickness (FT) burns were treated with NXB in a prospective, single arm, single-center, Phase II trial. Data was retrospectively retrieved and analyzed for efficacy of enzymatic eschar removal and surgical burden.

Thirty-three children under the age of 18, suffering from DPT to FT burns were treated with NXB or SOC as part of a Phase III, multinational, multi-center, open label, randomized, controlled clinical trial. Seventeen of these children were treated with NXB and 16 were treated according to SOC. Early end points included time to complete debridement, need for surgical excision and percentage of burn autografted. The Phase III patients also underwent long-term evaluation of scarring and quality of life.

Results: Phase II data shows that NXB efficiently removed the eschar in 92% of the areas treated, and only 34% of the debrided areas required skin-grafting. Graft take was 94.1%. The rest of the areas were healed by spontaneous epithelialization. Complete wound closure occurred after 21.4±16.5 days.

Phase III data shows that NXB efficiently removed the eschar (100% vs. 93.8% in SOC), significantly reduced the time to complete debridement (0.9±0.7 days vs. 6.5±5.9 days in SOC, p

Conclusions: Phase II data demonstrated the efficacy of NXB as an enzymatic debriding means. Phase III data further demonstrated that enzymatic debridement with NXB resulted in earlier eschar removal, reduced need for and extent of surgery compared with SOC while achieving comparable long-term results in children with deep burns.