Clinical Phase 2a Development of BX-001N for the Treatment of Acute Kidney Injury by Inhibiting Ischemia-Reperfusion Injury

BILIX

BILIX AVANT-GARDE THERAPY FOR INTRACTABLE DISEASES

OTHERS | **Phase 2**

Product Type	Others-Synth.
Indication	Cardiac Surgery-Associated Acute Kidney Injury (CSA-AKI)
Target	Reactive Oxygen Species (ROS; H2O2, O2-, •OH, others), Keap1
MoA(Mechanism of Action)	Antioxidation and immune modulation through direct ROS scavenging and indirect activation of Nrf2/HO-1 pathway by Keap1 modification
Competitiveness	First in Class: Published 23 papers containing the results of *in vivo* efficacy for 14 diseases using BX-001N Unique MoA: Both antioxidation and immune modulation Targeted Distribution: Preferential distribution to inflamed tissues and immune cells with enhanced permeability and retention effect Appropriate PK Profile: Longer half-life (124 h, Phase I) than small-molecule antioxidants (~5 h), yet shorter half-life with higher clearance than immunomodulating antibodies Good Safety Profile: Synthetic bilirubin, an endogenous substance, was conjugated with discrete PEG, resulting in nanoparticles. Tolerability was confirmed in rats (125 mg/kg/day NOAEL) and dogs (25 mg/kg/day NOAEL) in GLP 14-day repeat-dose studies and Phase I trial (7.5 mg/kg, single; 6 mg/kg, repeat/daily injection for 4 days)
Development Stage	Phase 2
Route of Administration	Intravenous administration