

F065 - Late-breaking Research: Procedural Dermatology

Saturday, March 5

1:12 PM

Safety, Efficacy and Duration of Effect of RT002, a Botulinum Toxin Type A for Injection, to Treat Glabellar Lines: The Phase 2 BELMONT Study / Jean Carruthers, MD, FRCSC, FRCS (Ophth)

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Learning Objective 1: In a head-to-head comparison, determine safety and efficacy of a single treatment of DaxibotulinumtoxinA for Injection (RT002) for moderate or severe glabellar lines vs. 150-kDa onabotulinumtoxinA (BOTOX®/VISTABEL®) 20U

Learning Objective 2: Assess the duration of a single treatment effect of RT002 at three dose levels vs. onabotulinumtoxinA

Learning Objective 3: N/A

Abstract

DaxibotulinumtoxinA for Injection (RT002) is designed for targeted delivery of botulinum toxin, while reducing spread beyond the injection site. This 24-week interim analysis (randomized, double-blind, multicenter) included adults (ITT: N=268) administered RT002 20U, 40U, 60U; placebo; or onabotulinumtoxinA (BOTOX®/VISTABEL®) 20U.

ITT: Week 4: response to all RT002 doses achieved 98.1%-100% >1-point IGA-FWS maximum frown and 84.9% and 96.2% response for >2-point IGA-FWS with RT002 40U and 60U, respectively. Week 16: RT002 40U and 60U achieved 73.6% (p=.037) and 84.9% response (p=.002), respectively for >1-point IGA-FWS vs. onabotulinumtoxinA 56.9%.

PP Week 24: With RT002 40U, there was a longer (23.6 median wks; p=.020) duration response vs. onabotulinumtoxinA (18.8 wks) based on >1-point IGA-FWS. IGA-FWS none-or-mild response with RT002 40U was 30.8% (p<.041) vs. onabotulinumtoxinA 11.9%. GAIS score >1 maximum frown response with RT002 40U was 37.7% (p=.049) vs. onabotulinumtoxinA 20.4%.

Treatments were well tolerated, with no serious adverse events and no cases of ptosis with RT002 40U. There were 3 cases of transient ptosis with RT002 60U, one with onabotulinumtoxinA, and none with RT002 20U. Injection site effects occurred with all treatments — highest was erythema with onabotulinumtoxinA (n=5). Analysis revealed favorable clinically meaningful differentiation with RT002 40U.

Reference(s)

Revance Therapeutics, Inc. Data on file, 2016.