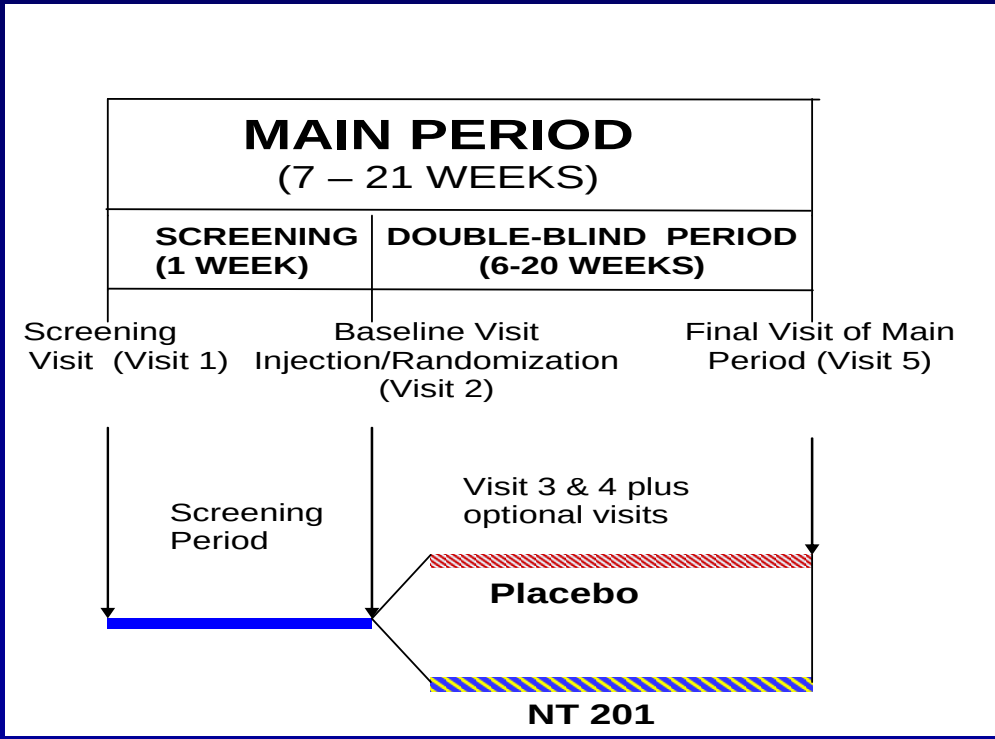
Efficacy and safety of NT 201 (Botulinum neurotoxin free from complexing proteins) in Blepharospasm.

Joseph Jankovic (1), Cynthia Comella (2), Angelika Hanschmann (3), Susanne Grafe (3) for the NT 201 BEB US study group
Baylor College of Medicine, Houston, Texas (1), Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois (2), Merz Pharmaceuticals, Frankfurt, Germany (3)

Subjects were randomly assigned to the NT 201 or the Placebo Group in a ratio of 2:1

Injection of up to 50 units NT 201 or placebo per eye (based on the maximum approved dose in Europe) The Baseline injection had to be similar to the last two injections with Botox® directly prior to trial entry (+/- 10%) with respect to total dose, volume, dilution, injection points per muscle, and doses at each site



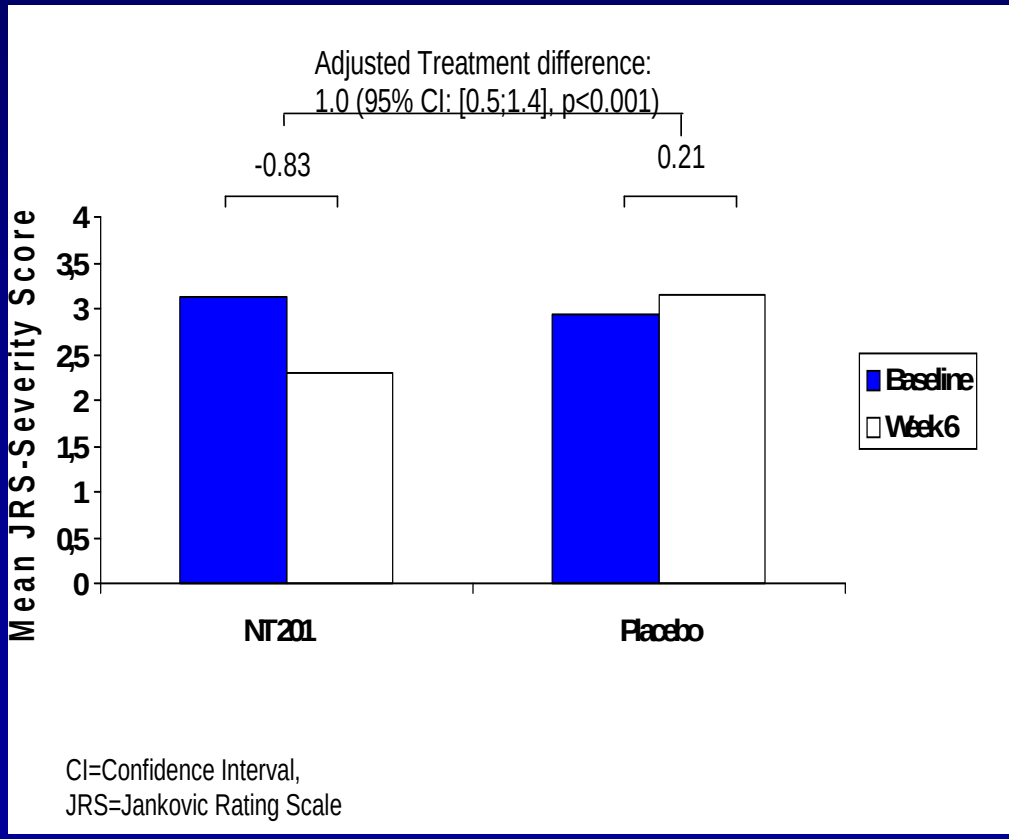
Primary Efficacy Parameters

Change from Baseline in Jankovic Rating Scale (JRS) severity subscore assessed by an independent blinded investigator 6 weeks after injection

Efficacy and safety of NT 201 (Botulinum neurotoxin free from complexing proteins) in Blepharospasm.

Joseph Jankovic (1), Cynthia Comella (2), Angelika Hanschmann (3), Susanne Grafe (3) for the NT 201 BEB US study group
Baylor College of Medicine, Houston, Texas (1), Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois (2), Merz Pharmaceuticals, Frankfurt, Germany (3)

Of the 109 blepharospasm patients the treatment difference in the JRS severity subscore was statistically significant in favor of NT 201 ($p<0.001$). The beneficial effects of NT 201 were also supported by all secondary endpoints. The most commonly reported AEs of NT 201 vs placebo were eyelid ptosis (18.9 vs. 8.8%), dry eye (16.2 vs. 11.8%), and dry mouth (16.2 vs. 2.9%).



CI=Confidence Interval,
JRS=Jankovic Rating Scale

Efficacy and safety of NT 201 (Botulinum neurotoxin free from complexing proteins) in Blepharospasm.

Joseph Jankovic (1), Cynthia Comella (2), Angelika Hanschmann (3), Susanne Grafe (3) for the NT 201 BEB US study group
Baylor College of Medicine, Houston, Texas (1), Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois (2), Merz Pharmaceuticals, Frankfurt, Germany (3)

- NT 201 administered in a mean overall dose of about 66.9 Units proved to be therapeutically effective in the treatment of blepharospasm.

- NT 201 was well tolerated by subjects with blepharospasm and there was no evidence of any clinically relevant safety finding.