

## **Upneeq™ (oxymetazoline hydrochloride ophthalmic solution), 0.1%**

### **Medical Information Response Document**

#### **Bell's Palsy**

Upneeq is indicated for the treatment of acquired blepharoptosis in adults.<sup>1</sup> It is not indicated for the treatment of ptosis associated with Bell's palsy (idiopathic, unilateral palsy of the 7<sup>th</sup> cranial (facial) nerve, with an acute onset).

In the Upneeq phase 3 clinical trials, prospective subjects with any history of Bell's palsy were able to proceed with screening if the condition had resolved with no residual effect and an end date had been noted. Among the 538 total subjects enrolled in the phase 3 trials, 4 had Bell's palsy / facial paralysis noted in their pre-study medical history (n=2 subjects each in one of the 6-week efficacy trials (Study RVL-1201-202) and the 12-week safety trial (Study RVL-1201-203)).<sup>2,3</sup> All four of these subjects received Upneeq, however no *post hoc* statistical analysis was carried out to assess the effect of treatment in this small subgroup of subjects. Additionally, no discernable safety signal was noted.

#### **References**

1. Upneeq™ (oxymetazoline hydrochloride ophthalmic solution), 0.1% [package insert]. Bridgewater, NJ: RVL Pharmaceuticals, Inc.; 2020.
2. Osmotica data on file. Clinical Study Report. Study RVL-1201-202: A randomized, double-masked, placebo-controlled phase 3 study of the efficacy and safety of RVL-1201 in the treatment of acquired blepharoptosis. July 8, 2019.
3. Osmotica data on file. Clinical Study Report. Study RVL-1201-203: A randomized, double-masked, placebo-controlled phase 3 study of the safety of RVL-1201 in the treatment of acquired blepharoptosis. July 8, 2018.

