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| Study title/design: A multicenter, open label long-term safety study of BHV3000 in the acute treatment of migraine | |
| Trial | NCT03266588: https://clinicaltrials.gov/ct2/show/NCT03266588?term=rimegepant&rank=3 |
| Aim | To evaluate the safety and tolerability of BHV3000 (rimegepant) |
| Study design | An estimate 2000 patients will be enrolled in the single group assessment of rimegepant |
| Patient population | Patients 18 years and older with:  4-14 moderate to severe migraines/month  Onset of migraines prior to 50 years of age  Migraine attacks, on average, lasting 4-72 hours if untreated  Ability to distinguish migraine attacks from tension/cluster headaches  Patients with contraindications for use of triptans may be included provided they meet all other study entry criteria |
| Primary efficacy endpoint | Frequency and severity of adverse events and discontinuations due to adverse events during 52 weeks treatment (treatment-emergent adverse events as assessed through laboratory tests, ECGs, physical exam findings) |
| Other endpoints | ALT or AST > 3x ULN with total bilirubin >2x ULN during 52 weeks treatment  Hepatic related adverse events and hepatic related adverse events that lead to discontinuation during 52 weeks |
| Key results | Study start date: August 30, 2017  Estimated primary completion date: June 2019  Estimated study completion date: July 2019 |
| Author conclusion | Awaiting results. |
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