Migraine | Pharmacor | G7 | 2014

Last Updated 4 December 2014 The migraine market consists of a multitude of therapies that either acutely treat migraine attacks or serve as prophylactic treatment. Among acute antimigraine therapies, triptans and NSAIDs/general analgesics are the most extensively prescribed. All the available triptan products, which constitute more than 60% of the total migraine major-market sales in 2013, have or will face generic competition during our 2013-2023 forecast period. However, the sales losses accompanying such generic competition will be countered by the uptake of emerging acute therapies—including several reformulations of existing products—and coupled with forecasted increases in both the acute and prophylactic drug-treated populations, the migraine market will grow from nearly $ billion in 2013 to more than $ billion in 2023. Despite the widespread genericization of the acute treatment market—the greatest extent will occur by the midyear of our forecast period—opportunity exists for acute antimigraine therapies that can offer improved efficacy over available triptans, or that can offer nontriptan pharmacological options to patients who do not respond to triptans or in whom triptans are contraindicated, (those with cardiovascular risks). The most commercially promising emerging therapies, Allergan’s orally inhaled dihydroergotamine (DHE; Semprana [formerly Levadex]) and CoLucid’s 5-HT 1F receptor agonist lasmiditan, will only partially fill the unmet need for acute nontriptan agents, yet each is forecast to garner significant peak-year sales. However, although a greater unmet need exists for new prophylactic therapies, we do not forecast any new prophylactic therapies to launch during the forecast period. Allergan’s onabotulinumtoxinA (Botox) is the branded prophylactic therapy currently available, and even though its use will largely be restricted to the chronic migraine population, we expect the drug will garner more than $810 million in major-market sales in 2023, demonstrating the commercial opportunity for premium-priced therapies that offer alternatives (particularly with improved tolerability) in the otherwise generic prophylactic market.

Questions Answered in This Report:

- The genericization of the triptan class continues, and all available triptans—including most available reformulations—will experience generic competition by 2023. How influential is cost in the prescribing of migraine treatments? What opportunities exist for new acute agents seeking premium pricing in this genericizing market? How receptive will prescribers be to premium-priced agents, and what factors will drive prescribing such therapies?

- Interviewed experts continue to express enthusiasm about emerging nontriptan options. What is the potential for new nontriptan therapies in the acute treatment of migraine? How
do interviewed experts expect orally inhaled DHE and lasmiditan to be incorporated into the migraine treatment algorithm in the face of strong generic competition from many time-tested products?

- Many drug developers are focusing on reformulations (e.g., transdermal patches, oral films, oral or nasal inhalation) of available antimigraine products to target patients inadequately served by available formulations. **How popular are non-oral tablet formulations today? How are such agents utilized? What are the barriers to uptake of current non-tablet and non-oral formulations? Do any emerging reformulations offer advantages over available triptan formulations (e.g., more rapid onset, improved efficacy)? What is the commercial potential for novel triptan reformulations?**

- Despite competing in an otherwise generic prophylactic market, onabotulinumtoxinA will experience increased major-market commercial success through 2023 for prevention of chronic migraine (CM). Despite reimbursement restrictions and the need for administration by trained professionals, it offers an efficacious and tolerable alternative for non-responders to available oral prophylactics. **How large is the market for CM prophylaxis across the seven major markets? How efficacious and tolerable are current prophylactic agents, and what unmet needs remain in this market?**

**Scope:**

**Markets covered:** United States, France, Germany, Italy, Spain, United Kingdom, Japan.

**Primary research:** 29 country-specific interviews with neurologists and headache specialists.

**Epidemiology:** Number of total prevalent cases of episodic migraine (EM) and chronic migraine (CM). Number of total 12-month, diagnosed, and acutely drug-treated prevalent cases of EM and CM. Number of total 12-month, diagnosed, and prophylactically drug-treated prevalent cases of EM and CM. Number of prevalent cases of EM by severity. Number of total EM events.

**Population segments in market forecast:** Four populations are covered, comprising acute treatment and prophylactic treatment among episodic migraineurs and chronic migraineurs.

**Emerging therapies:** Phase II: 12 drugs; preregistered/registered: 5 drugs. Coverage of 10 preclinical/discovery and Phase I products.

**Market forecast features:** We forecast future trends in the markets for the acute and prophylactic treatment of EM and CM from 2013 to 2023, taking into account several anticipated new product launches and impending generics competition.

**Alternative market scenarios:** Allergan receives European approval for its orally inhaled DHE; Alder Biopharmaceutical’s calcitonin gene-related peptide-targeted monoclonal antibody ALD-403 is approved for the prophylactic treatment of both CM and EM.
Report Details

- **Pub Date:** December 2014
- **Author(s):** ["Angela M. Sparrow, Ph.D.
  Wouter van der Plujm, M.P.H.
  Margaret Weigel"]