



Market release
20 July 2017

AFT Pharmaceutical's painkiller *Maxigesic* now licensed in 124 countries worldwide

AFT Pharmaceuticals ('AFT') has added to its existing agreements in concluding an alliance with a private European pharmaceutical company, Amicus SA Switzerland ('Amicus'), for the licensing of the product line of its patented combination painkiller, *Maxigesic*, in 3 regions: the Baltics (Latvia, Estonia and Lithuania); Central Eastern Europe (Czech Republic, Hungary, Bulgaria, Romania and Slovakia); and most of the Balkans (Croatia, Slovenia, Serbia, Montenegro, Bosnia and Macedonia).

"We had previously disclosed our target to sell *Maxigesic* in 100 countries in our product disclosure statement," says AFT CEO, Dr Hartley Atkinson. "This agreement, together with other recent out-licensing agreements, means that *Maxigesic* is now licensed in 124 countries around the world. Getting these agreements in place shows that we are expanding on our planned pathway to deliver on our sales targets."

Currently *Maxigesic* is sold in eight countries. AFT has previously informed the market that it anticipates registration and product launches covering existing agreements will occur on a phased basis in these countries according to the following approximate schedule: around one-third in FY2018, around one-quarter in both FY2019 and FY2020, and the balance in FY2021.

Dr Atkinson expects that some additional launches from this current deal will take place within the closing period of the FY2018 financial year. This outcome will depend on how quickly the transfer of licenses to Amicus proceeds in some of the nations where a license has already been granted. Additional regulatory filings will also occur in Montenegro, Bosnia, Macedonia and Lithuania as soon as possible.

Maxigesic consists of a patented, fixed ratio of ibuprofen for anti-inflammation management and paracetamol (also called acetaminophen) for pain management. *Maxigesic* products covered by this new agreement will include tablet, sachet, oral liquid, fast-dissolve and dry powder sticks.

"We believe that these markets present good additional potential for *Maxigesic* as the market, defined by *IMS Health* for Paracetamol and Ibuprofen tablet sales for ten of the 14 countries, is in excess of US\$220M," says Dr Atkinson.

"Amicus is a good potential partner as its business teams have an excellent track record already in these complex markets. Amicus is a young, innovative and rapidly growing company with great OTC and RX market access in these specialised markets," adds Dr Atkinson.

"This agreement with AFT marks another breakthrough for Amicus as a company," commented Amicus Board Member and co-Founder, Petr Nemec. "The AFT relationship covers virtually all of Amicus' existing territory as well as several new countries that we intend to enter – meaning that *Maxigesic* will spearhead Amicus' entry into territories such as Hungary, Bulgaria and Czech Republic, as well as build on our strong OTC presence in existing Amicus countries."

Amicus CEO Jean-Michel Lespinasse commented that "Amicus was honoured to be selected by AFT as its long-term licensing partner across a large central European territory. We are excited to be able to roll-out a novel pain reliever with both an efficacy and safety claim," Lespinasse continued, pointing out that "*Maxigesic* marks a strategic evolution for Amicus, whereby we are licensing, long-term, a novel combination and building real value for the company. We look forward to successful launches in early 2018 and to build *Maxigesic* into a major brand in the territory."

Licensing agreement with Expanscience

In May, AFT Pharmaceuticals announced an agreement with a French pharmaceutical company to out-license the product line of *Maxigesic* to France, Monaco, Andorra and French dependencies DOM TOMs.

At that time, French labour laws prohibited AFT from disclosing the name of the French company. In compliance with French law, AFT can now inform the market that the agreement is with the French pharma company *Laboratoires Expanscience* headquartered in Courbevoie, France.

Adding to the significance of the May agreement, the new French Minister of Health, Agnès Buzyn, announced last week that opioid derivatives, including codeine, will be added to France's list of prescription-only medicines.¹ The decision will have immediate effect. Previously, codeine-based painkillers had been available without prescription in certain strengths.

Hartley Atkinson says that the timing of the regulatory change in France is significant, particularly given that France represents the world's second biggest market for paracetamol and ibuprofen tablet sales.

"There are three important things that have come together here," says Dr Atkinson.

"First, *Maxigesic* was recommended for regulatory approval by the European Medicine Agency in May. Second, in the same month we signed a licensing agreement for *Maxigesic* with *Expanscience* which is a high-calibre local French pharma company. And third, France has just joined the growing list of countries shifting codeine-based painkillers to prescription only, meaning that this will improve the sales prospects for codeine-free *Maxigesic*."

The New Zealand regulatory agency Medsafe, through its Medicines Classification Committee, is currently also considering a proposal to harmonise New Zealand regulation with Australia by up-scheduling codeine-based painkillers to prescription-only based on the risks of misuse and addiction.

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About Amicus A.G.

Amicus subsidiaries operate in the Balkan and Baltic countries of Croatia, Estonia, Kosovo, Latvia, Lithuania, Macedonia, Montenegro, Serbia, Slovenia, and now also

¹ "Codeine now restricted to prescription only" (13 July 2017) *The Connexion: French News*

Hungary. Set up in 2014, Amicus has gathered outstanding pharmaceutical talent, including long experience in the OTC / consumer healthcare. The company specialises in representing research-based specialty pharmaceuticals, (licensed and pre-registered, imported under special license), as well as self-care brands.

For more information about Amicus, please visit: www.amicuspharma.eu