Following the completion of the Phase 1 trial and Phase 2A enabling activities, Servier has an exclusive option to license GLPG1972.

MOR106 (IL-17 antibody): Atopic Dermatitis

Galapagos, in collaboration with MorphoSys, is developing MOR106 (IL-17c antibody), a Phase 1 clinical candidate for moderate to severe Atopic Dermatitis. Atopic dermatitis is a chronic and relapsing inflammatory skin condition, and those with AD are also susceptible to infections and cutaneous colonization. Atopic dermatitis is usually abated with avoidance of allergens and irritants, skin cleansing, and 1st line emollient therapy. In patients failing these local therapies, systemic immunosuppressants like cyclosporine A, methotrexate, azathioprine, mycophenolate mofetil are introduced as it is theoretically thought that secondary bacterial skin infections may underlie the severity of the disease by triggering an exaggerated T-cell response.

Standard therapies simply ameliorate the symptoms but do not address the underlying cause of the disease so biologics are being increasingly welcomed into the treatment paradigm. Clyclosporine A, a calcineruin inhibitor that blocks T-cell activation, is considered as 1st line therapy in severe cases of AD, while methotrexate, azathioprine, and mycophenolate mofetil are generally used off-label as 2nd line therapies when cyclosporine is ineffective or if there is intolerance or contraindications. In addition to being used off-label, these drugs are associated with severe side effects, especially in young children which make up a sizable part of the patient population. Omalizumab (anti-IgE antibody), rituximab (anti-CD20), and etanercept (anti-TNF-α) have all been used off-label as physicians seek alternative therapies, but Dupixent (duplimumab), an anti-IL-4Rα was the first and only biologic approved for moderate to severe AD.

The atopic dermatitis market is quite large, and management has highlighted analysis from GlobalData which suggest at least 10 million patients being treated for AD in the 7 major markets. Our own analysis suggests ~3million moderate-severe AD patients in the US, with approximately 50% (~1.6 million) having inadequately controlled disease. Dupixent, which was recently launched, is expected to reach up to $3-5 billion in sales due to potential for approval in other inflammatory indications (allergies, asthma, etc). MOR106 which targets IL-17c, is also expected to have broad efficacy as shown by COSENTYX (secukinumab) an anti-IL-17a antibody, approved for plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis. COSENTYX has also reached blockbuster status (>$1.1bn) despite strong competition from other psoriasis drugs like Stelara, Humira, and Embrel.

The mechanism of action of MOR106 is highly validated, as the IL-class makes up a huge percent of marketed drugs for inflammatory conditions, but we await additional data to allow for model inclusion. IL-17C stimulates epithelial inflammatory responses similar to those induced by IL-17A, but IL-17C inhibition is expected to be more selective for the epithelia cells and thus be associated with lesser side effects.[31] The primary completion date for the ongoing Phase 1 study (NCT02739009) of MOR106 in ~80 patients is July 17 so we would also expect data by YE2017.

[31] Ramirez-Carrozzi et al. IL-17C regulates the innate immune function of epithelial cells in an autocrine manner. Nat Immunol. 2011 Oct 12;12(12):1159-66

Collaboration and Licensing:

Galapagos has development partnerships for all clinical candidates with co-promoting or royalties based agreements in place. Potential milestone payments could be up to ~$2bn.

Figure 57. Development Partnerships

Established	Company	Type of Agreement	Terms of Agreement
2015	Gilead	Development & Commercialization Agreement: Filgotinib for Inflammatory and Autoimmune Diseases	• GLPG received upfront licensing fee of $300mm + $425mm equity investment + potential for $1.35bn in milestone payments • GLPG co-funds 20% of development activities & Gilead is responsible for further development, manufacturing, & WW marketing and sales • GLPG can opt to co-promote filgotinib in the UK, Germany, France, Italy, Spain, Belgium the Netherlands, and Luxembourg for a 50/50 split of the profits • Tiered royalties starting at 20% in non-copromote territories
2013	Abbvie	Development & Commercialization Agreement: Potentiators and Correctors for Cystic Fibrosis	• GLPG received upfront licensing fee of $45mm+ potential for $570mm in milestone payments • GLPG co-funds 100% of development activities up to Phase 2, and Abbvie is responsible for Phase 3 with financial contribution from GLPG • GLPG opt to co-promote filgotinib in Belgium, the Netherlands, and Luxembourg for a 50/50 split of the profits with full rights to China and South Korea • Tiered royalties starting from 15-20% in non-copromote territories
2010	Servier	Discovery and Development Agreement: Osteoarthritis Drug Targets	• GLPG received research access payment of €7mm+ potential for €290 mm in milestone payments • GLPG funds 100% of development activities up to Phase 1, at which time Servier can opt to exclusively license the molecule • GLPG retains US commercialization rights • Royalties on Commercial Sales ex-US
2008	Morphosys	Discovery and Development Agreement: Inflammatory Bone & Joint Conditions	• Galapagos will provide antibody targets implicated in bone and joint disease, in addition to its adenoviral target discovery platform • Morphosys will use it's HuCaL technology to generate the fully human antibodies • 50/50 split of all research & development costs, and profits

Source: Company Reports, Bloomberg, BTIG Research Estimates, June 2017

Management Overview

The management team is led by Onno van de Stolpe, who founded the company in 1999 as a joint venture between Crucell and Tibotec. Members of the management team (Figure 58) have all had successful careers in Biotech, and recent additions to the team are highly aligned with the expected growth of the company, as major candidates approach late stage clinical and commercial development.

Figure 58. Galapagos Executive Management

Executive Team	Position	Description
Onno van de Stolpe	Chief Executive Officer	Onno van de Stolpe founded Galapagos in 1999 and has served as the CEO, and as a member of the board of directors since it's inception. Prior to founding Galapogos, he held leadership roles at IntroGene NV (later Crucell NV), which supported the launch of Galapagos through a joint venture with Tibotec. Before joining IntroGene, he was a MD at Molecular Probes Europe BV where he was instrumental in establishing their European Headquarters. Onno also draws extensively from his time in Business Develop at MOGEN International NV in Leiden, and holds a Masters degree from Wageningen University.
Andre Hoekema, PhD	Senior Vice President Corporate Development	Andre Hoekema joined Galapagos in 2005 from Invitrogen Corporation, were he was managing director of Corporate Development (Europe). He has also held leadership roles at Crucell, and Molecular Probes, and brings over 20 years of experience in biotech. Andre holds a PhD from Leiden University and is a listed inventor on multiple patents.
Bart Filius, MBA	Chief Financial Officer	Bart Filius joined Galapagos in 2014 from Sanofi Europe, where he was CFO. While as Sanofi, Bart held numerous roles including VP for Mergers and Acquisitions and was instrumental in transforming the Sanofi European organization. Prior to joining Sanofi, Bart was a strategy consultant at Arthur D Little, and he holds a MBA degree from INSEAD.
Walid Abi-Saab, MD	Chief Medical Officer	Walid Abi-Saab recently joined Galapagos in March 2017 to drive the medical strategy as major candidates approach late stage clinical development, based on his track record of bringing over 30 molecules through the approval process. Prior to joining Galapagos, Walid was at Shire where he was VP of the Global Clinical Development Group. Before joining Shire, he also held clinical development roles at Novartis, Abbott, and Pfizer. Early in his career, Walid was a professor at Yale School of Medicine and hold a MD from Universite Saint Joseph in Beirut, Lebanon.
Piet Wigeerinck, PhD	Chief Scientific Officer	Piet Wigerinck joined Galapagos in 2008 from Tibotec, where he was VP of Drug Discovery and a member Management Board. He is a trained medical chemist and has over 15 years of research and development experience with bringing drugs to the clinic, including time at both Tibotec and Janssen. Piet holds a PhD from KU Leuven and is a listed inventor on multiple patents.

Source: Company Reports, Bloomberg, June 2017

Company Overview

Galapagos is a biopharma company specializing in the discovery and development of small molecule drugs, using their proprietary target discovery platform. One of the clinical candidates is a highly selective inhibitor of Jak1, a key player of the inflammatory signalling cascade, and this molecule has been licensed by Gilead and is now in several Phase 3 studies across multiple indications including Crohn's, ulcerative colitis, and rheumatoid arthritis (Figure 59). Ongoing preclinical and Phase 1-2 clinical studies in cystic fibrosis are also underway with various small molecules targeting novel mechanisms that could address 90% of patients with the cystic fibrosis transmembrane receptor (CFTR) mutation - the CF portfolio is being developed in partnership with AbbVie. Galapagos is headquartered in Mechelen, Belgium with facilities in the Netherlands, France, and Croatia.

Figure 59. Galapagos Clinical Pipeline

	Phase 1	Phase 2	Phase 3
JAK1 inhibitor Filgotinib		• Short Bowel CD • Fistualizing CD • Sjogren's Syndrome • Ankylosing Spondylitis • Psoriatic Arthritis • Cutaneous Lupus Erythematosus	• Rheumatoid Arthritis • Crohn's Disease • Ulcerative Colitis
Potentiator '1837		• Cystic Fibrosis	
Potentiator '2451+'2222	• Cystic Fibrosis		
Potentiator '3067	• Cystic Fibrosis	• Cystic Fibrosis	
C1 Corrector '2222		• Cystic Fibrosis	
C1 Corrector '2851	• Cystic Fibrosis		
C2 Corrector '2737		• Cystic Fibrosis	
C2 Corrector '3221	• Cystic Fibrosis		
ADAMT5 inhibitor '1972	• Osteoarthritis		
IL-17 inhibitor MOR106	• Atopic Dermatitis		
Autotaxin inhibitor '1690		• Idiopathic Pulmonary fibrosis	

C1 – early binding correctors
C2 – late binding correctors
ADAMT5 - A Disintegrin and Metalloproteinase with Thrombospondin Motifs 5

Source: Company Reports, June 2017

Key Risks to Our Ratings and Recommendation

Our Buy rating and $98 price target may prove inaccurate due to a number of risks related to Galapagos (GLPG) being an early stage company with limited clinical data across key indications:

- Our valuation is heavily reliant on revenues from the CF portfolio which carry substantial risks including failure to show efficacy in larger studies, or in the case of pre-IND molecules, failure to show unacceptable levels of efficacy or toxicity when tested in humans.

- Regulatory approval for filgotinib or candidates within the CF portfolio may not occur within our current timeline, as US FDA or European approval is not guaranteed and the company may need to run additional studies not currently contemplated within our clinical development timeline.

- The company relies on outside capital including strong reliance on drug partnership revenues, and in the event that capital is not available, Galapagos could cease operations.