



This announcement contains inside information for the purposes of Article 7 of Regulation 596/2014.

Shield Therapeutics plc

("Shield" or the "Group")

Shield Therapeutics and Norgine B.V. (Norgine) enter into an exclusive licence agreement for the commercialisation of Feraccru® in Europe, Australia and New Zealand

- **Shield to receive an £11 million upfront licence payment**
- **Up to €54.5million in development and sales milestones, together with royalties ranging from 25% to 40%**
- **Shield retains full commercial rights to Feraccru® in all unlicensed countries including the USA**

London, UK, 19 September 2018: Shield Therapeutics plc (LSE:STX), a commercial stage, pharmaceutical company delivering innovative specialty pharmaceuticals to address patients' unmet medical needs and Norgine, a leading European specialist pharma company, today announced that they have entered into an exclusive licence agreement in Europe, Australia and New Zealand by which Norgine will commercialise Feraccru®, Shield's approved product for the treatment of iron deficiency in adults.

Under the terms of the agreement, Shield will receive an immediate £11 million upfront payment, is eligible to receive up to €4.5 million in short-term development milestones and up to €50 million in sales milestones upon the achievement of specified targets. Shield will also receive tiered royalties ranging from 25% to 40% of net sales of Feraccru®.

This long-term exclusive licence grants Norgine the right to commercialise Feraccru® in the UK, France, Germany, Italy, Spain and all other European countries which are not already covered by Shield's previously announced licence agreements with AOP Orphan Pharmaceuticals AG and Ewopharma AG, as well as in Australia and New Zealand (the "Licensed Territories").

Shield retains full ownership of the global intellectual property rights to Feraccru® including responsibility for the completion of the ongoing AEGIS-H2H study, a planned phase 3 paediatric study and any further significant development of the product. Shield also retains full commercial rights to Feraccru® in all countries not covered by the licence agreements with Norgine, AOP Orphan Pharmaceuticals AG and Ewopharma AG.

Within the Licensed Territories, Norgine will be responsible for obtaining and maintaining regulatory and pricing approvals as well as all commercial activities, including post-marketing studies; while Shield will be responsible for, and bear the costs of, manufacturing and supply.

The financial terms of the agreement significantly extend Shield's cash runway, enabling the Group to continue the development of Feraccru®, including the US NDA application, as well as pursue further opportunities to out-licence Feraccru® and exploit the Group's other assets.



Carl Sterritt, Chief Executive Officer of Shield Therapeutics, said: *"I am delighted to announce this agreement with Norgine, which will significantly accelerate the commercialisation of Feraccru® in Europe. They have an excellent track record of commercial success with specialty pharmaceutical products and we have been impressed with their determination to succeed in this competitive licensing process. With their established infrastructure and commercial expertise, they will be a valuable partner for Shield and Feraccru® and this agreement should quickly see many more patients in Europe benefiting from Feraccru's unique and outstanding characteristics, which differentiate it from existing oral and intravenous therapies for the treatment of iron deficiency.*

Furthermore, the transaction significantly extends Shield's previously reported cash runway, allowing us to continue the development of Feraccru in the USA and elsewhere and, with patent protection through 2035, it will allow our shareholders to have a significant share in the long-term success of Feraccru®."

Peter Stein, Chairman and Chief Executive Officer of Norgine, said: *"This agreement is an affirmation of our commitment to build a strong late-stage portfolio of transformative products for patients in Europe, Australia and New Zealand. We believe that Feraccru® is an important advance in the treatment of iron deficiency and we look forward to making Feraccru® a success for patients in need."*

- Ends -

Conference call for analysts

A conference call for analysts will be held at 11.30am BST on 19 September 2018

Dial in details:

Participant local dial-in:	+44 (0) 2071 928000
Participant free phone dial-in:	08003767922
Participant code:	8426797

To access the presentation, please visit Shield's investor relations page

<https://www.shieldtherapeutics.com/investors/presentations/>

An audio replay file will be made available shortly afterwards via the Company website:

www.shieldtherapeutics.com

For further information please contact:

Shield Therapeutics plc	+44 (0)207 186 8500
Carl Sterritt, Chief Executive Officer	
Tim Watts, Interim Chief Financial Officer	

Nominated Advisor and Joint Broker	+44 (0)203 100 2222
Liberum Capital Limited	
Christopher Britton/Steve Pearce	

Joint Broker	+44 (0)207 418 8900
Peel Hunt LLP	



James Steel/ Dr Christopher Golden

Financial PR Advisor

+44 (0)203 709 5700

Consilium Strategic Communications

Mary-Jane Elliott/Matthew Neal

Norgine B.V.

Paul Pay, Chief Business Development Officer

+44 (0)1895 453715

Isabelle Jouin, Communications

+44 (0)1895 826237

This announcement contains inside information for the purposes of Article 7 of Regulation 596/2014. The person who arranged for the release of this announcement on behalf of Shield Therapeutics was Carl Sterritt, Chief Executive Officer.

About Feraccru®

Feraccru® is a novel, stable, non-salt, oral formulation of ferric iron, which has a differentiated mechanism of action compared to salt-based oral iron therapies. When salt-based oral iron therapies are ingested, the iron must dissociate from the salt in the GI tract to allow the iron to be absorbed and treat the IDA. This free iron readily chelates to form insoluble clumps and produces damaging free radicals that together cause a range of mild-to-severe GI adverse events, including nausea, bloating and constipation, leading to poor tolerability, reduced patient compliance and ultimately treatment failure. In addition, many patients with IDA are concurrently treated with medicines that raise the pH in the gut which further reduces the effect of salt-based oral iron therapies as they require highly acidic conditions to be absorbed. Feraccru® is not an iron salt, and iron can be absorbed from the ferric maltol molecule, and as a result, it does not routinely cause the same treatment-limiting intolerance issues. Feraccru® has been shown in clinical trials to be well-tolerated by patients even when they had previously failed treatment with salt-based oral iron therapies, which should lead to increased patient compliance and better patient outcomes.

Currently, the only treatment option for IDA patients who cannot tolerate salt-based oral iron therapies, is IV iron therapy. IV iron therapies quickly increase iron stores via direct administration of very large doses of iron, causing an increase in Hb levels that is physiologically controlled and occurs over a period of weeks, as is the case with Feraccru®. IV iron therapies, however, are invasive, costly, inconvenient and complex to administer, and also come with potentially life-threatening, spontaneous hypersensitivity reactions.

Feraccru® has been approved by the European Commission for the treatment of iron deficiency in adults, with or without anaemia.

About Shield Therapeutics plc

Shield is a commercial stage, pharmaceutical company delivering innovative specialty pharmaceuticals to address patients' unmet medical needs. Our clear purpose is to help our patients become people again, by enabling them to enjoy the things that make the difference in their everyday lives. The Group has a marketed product, Feraccru®, for the treatment of iron deficiency in adult patients with or without anaemia. Feraccru® has exclusive IP rights until the mid-2030's. For more information please visit www.shieldtherapeutics.com.



About Norgine

Norgine is a leading European specialist pharmaceutical company with a direct commercial presence in all major European markets. In 2017, Norgine's total net product sales were EUR 345 million, up 17 per cent. Norgine employs over 1,000 people across its commercial, development and manufacturing operations and manages all aspects of product development, production, marketing, sale and supply with a commercial focus on gastroenterology, hepatology, cancer and supportive care.

Norgine is headquartered in the Netherlands and owns a R&D site in Hengoed, Wales plus two manufacturing sites in Hengoed, Wales and Dreux, France. For more information, please visit www.norgine.com

In 2012, Norgine established a complementary business Norgine Ventures, supporting innovative healthcare companies through the provision of debt-like financing in Europe and the US. For more information, please visit www.norgineventures.com.

NORGINE and the sail logo are trademarks of the Norgine group of companies.

Forward-Looking Statements

This press release contains forward-looking statements. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements. These forward-looking statements are based on management's current expectations and include statements related to the timing of future results of Feraccru trials and the timing and success of the Group's regulatory plans and commercial strategy for Feraccru. These statements are neither promises nor guarantees, but involve known and unknown risks and uncertainties, many of which are beyond our control, that may cause actual results, performance or achievements to be materially different from management's expectations expressed or implied by the forward-looking statements, including, but not limited to, risks associated with the regulatory approval process, the Group's business and results of operations, competition and other market factors. The forward-looking statements made in this press release represent management's expectations as of the date of this press release, and except as required by law, the Group disclaims any obligation to update any forward-looking statements contained in this release, even if subsequent events cause our views to change.