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*An analyst briefing will be held at 14:00 UK time today at Buchanan Communications, 45 Moorfields London, EC2Y 9AE. Simultaneous to the meeting, there will be a live audio web cast of the presentation. To connect to the web cast facility, please go to [www.renovo.com](http://www.renovo.com) or [www.citycomments.co.uk](http://www.citycomments.co.uk) approximately 5 minutes (13:55) before the start of the briefing.*

*The presentation will also be available via a live conference call. Dial-in details are as follows: live participant number: +44 (0)20 8609 1435, participant PIN code 640835#. A replay of the conference call will be available for one month. Details are as follows: replay number: +44 (0) 20 8609 0289, replay confirmation code: 207378#.*



**RENOVO GROUP PLC**  
**(“Renovo” or “the Company”)**

**RENOVO ANNOUNCES JUVISTA<sup>®</sup> PHASE 2 TRIAL RESULTS  
IN SCAR REVISION AND BREAST AUGMENTATION SURGERY**

Renovo Group plc (LSE: RNVO), the biopharmaceutical company developing drugs for the reduction of scarring and acceleration of healing, today announces two Phase 2 clinical trial results for its lead drug, Juvista (human recombinant TGFβ3) in scar revision (RN1001-1009) and breast augmentation (RN1001-1010) surgery.

**Summary**

Renovo is pleased to announce the scar revision trial, where Juvista was dosed twice, met its primary endpoint with statistical significance. The breast augmentation trial, where Juvista was dosed once, did not meet its primary endpoint. In view of this new data and previous trials that have already reported Renovo believes that Juvista’s efficacy is greater when administered twice.

Based on these results Renovo plans to commence the European Phase 3 programme with a scar revision surgery trial. As previously guided, this first European Phase 3 trial will start in the second half of 2008. Two dose levels of Juvista are likely to be tested (200ng and 500ng) given twice, the first at the time of surgery following wound closure and the second 24 hours later. Scar revision is a procedure performed by Plastic Surgeons and Cosmetic Dermatologists for both patients wanting cosmetic improvements and those with serious disfiguring scars.

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Renovo will provide guidance on the design of this trial and the remainder of the Phase 3 programme for the European Regulatory Filing/Dossier following further consultation with both Shire and the relevant regulatory authorities

Renovo's strategy remains firmly focussed on accessing all segments of the substantial global market for the reduction of scarring in the skin. Accordingly Renovo is currently working to update its Juvista clinical development and commercialisation plans in order to achieve this objective.

The Company is well funded (net cash position at 31 December 2007: £93.8m) and has a broad portfolio of drugs with different mechanisms of action. Zesteem<sup>®</sup>, Renovo's lead drug for the acceleration of wound healing in the skin, will report Phase 3 clinical data in the second half of 2008.

### **Scar Revision Phase 2 Trial (RN1001-1009)**

- This trial consists of two groups of 30 patients; the first group reports today
- Primary endpoint was met with statistical significance ( $p=0.028$ )
- Efficacy was demonstrated in poorer scars than previously studied
- Efficacy was demonstrated in larger scars than previously studied

This trial was a randomised, double-blind, within-patient, placebo controlled Phase 2 study to investigate the safety and efficacy of 200ng per 100 $\mu$ L per linear cm of wound margin of Juvista given twice, at the time of surgery following wound closure and 24 hours later.

The study was divided into two groups in order to evaluate the efficacy of Juvista in two different scar revision surgical procedures, both of which involved 30 male and female patients, giving a total trial size of 60 patients.

Renovo is pleased to announce that the first group of the trial, in which the scar being revised is fully excised in one surgical procedure, met its primary endpoint with statistical significance ( $p=0.028$ ). This assessment was based on a photographic evaluation by a lay panel over a time period from week 6 to month 7 post surgery using a visual analogue scale (VAS).

The second group of 30 patients, in which a two stage surgical excision procedure is employed, will report in the second half of 2008.

Renovo plans to start its first Phase 3 trial in scar revision surgery in the second half of 2008.

### **Breast Augmentation Phase 2 Trial (RN1001-1010)**

This trial was a randomised, double-blind, within-patient, placebo controlled Phase 2 study to investigate the safety and efficacy of 50 and 200ng/100 $\mu$ L/linear cm of wound margin of Juvista administered once immediately following surgery to around 30 female patients in each dosage group, giving a total trial size of 63 patients.

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The trial did not meet its primary endpoint, which was assessment of standardised photographs of the scars by a lay panel 12 months post surgery using a VAS. Differences between drug and placebo were generally slight and in some cases statistically favoured placebo.

Renovo believes that the magnitude of efficacy of Juvista when given once at the time of surgery is reduced compared to twice dosing, at the time of surgery following wound closure and 24 hours later. Renovo concludes that 200ng/100µL/linear cm of wound margin dosed once is not sufficient to establish efficacy in the setting of breast augmentation.

### **Safety Profile**

The safety and tolerability profile to date, including the scar revision and breast augmentation trials, continues to support progressing Juvista into Phase 3 development.

### **Renovo's Future Plans for Juvista**

Following the results of the two trials reporting today, along with data from previous trials including RN1001-0036 (incisions) and RN1001-1007 (skin graft donor sites), Renovo believes that Juvista's efficacy is greatest when administered twice.

Based on the positive results from the first group of the Phase 2 scar revision trial Renovo, in connection with the preparation of the European regulatory dossier, plans to commence a first Phase 3 trial in scar revision surgery in the second half of 2008. This trial will be conducted across multiple international centres and likely evaluate two doses of Juvista (200ng and 500ng) given twice, at the time of surgery following wound closure and 24 hours later. Scar revision is a procedure performed by Plastic Surgeons and Cosmetic Dermatologists for both patients wanting cosmetic improvements and those with serious disfiguring scars.

Renovo will provide guidance on the design of this trial and the remainder of the Phase 3 programme for the European Regulatory Filing/Dossier following further consultation with both Shire and the relevant regulatory authorities.

Renovo's strategy remains firmly focussed on accessing all segments of the substantial global market for the reduction of scarring in the skin. Accordingly Renovo is currently working to update its Juvista clinical development and commercialisation plans to achieve this objective.

### **Professor Mark Ferguson, Chief Executive Officer of Renovo, commented:**

*"We are pleased that Juvista has achieved statistical significance in the first group of the scar revision trial.*

*"Although it is disappointing that the breast augmentation trial did not meet its primary endpoint, one of the objectives of our Phase 2 programme was to investigate the most effective dosing strategy for Juvista. Cumulatively the*

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*trials reported to date indicate that twice dosing yields greater efficacy than once dosing.*

*“This gives us confidence that the large scar reduction market remains accessible with Juvista and our first Phase 3 trial will start in the second half of 2008.”*

**For further information please contact:**

**Renovo**

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**Trial RN1001-1009 overview**

This trial was a randomised, double-blind, within-subject, placebo controlled Phase 2 study to investigate the safety and scar improvement efficacy of Juvista in 60 male and female subjects, aged 21 to 78, following scar revision surgery.

The trial was split into two equal groups of 30 patients in order to assess the efficacy of Juvista in two surgical scar revision procedures. The first group, where the entire scar was excised and the resultant wound closed in one procedure, reported today. The second group, where the scar is excised in stages, will report in the second half of 2008.

Patients in both groups had scars of at least 5cm in length deemed suitable for surgical revision by excision and direct closure. The area to be revised was split into three segments, consisting of a central section (of at least 3cm) and two end segments of equal length. Scars 9cm or longer were divided into three equal segments.

In the first group 200ng/100µL/linear cm of Juvista was administered intradermally at the time of surgery following wound closure and 24 hours later into both margins of one end segment of the wound. The other end segment received placebo at the same times, leaving an untreated (or ‘buffer’) segment in the middle, which received standard care only.

For the second group of patients there was a two step surgical procedure. During the first step the two end segments of the scar were excised and the resultant wounds closed. As with the first group 200ng/100µL/linear cm of Juvista was administered intradermally at the time of surgery following wound closure and 24 hours later into both margins of one end segment. The other end segment was treated with placebo in an identical manner and at the same times. Seven months after the original scar

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revision surgery, the middle segment of the scar was surgically excised in a second procedure, the wound closed and treated with standard care only.

For both groups all scars are photographed under standard conditions at week 6 and months 3, 4, 5, 6, 7, 9 and 12. The primary endpoint of the trial is the appearance of the scars as assessed by an independent panel of lay people (to simulate customers) using a visual analogue scale (VAS) over a time period from week 6 to 7 months post surgery.

### **Trial RN1001-1010 overview**

This trial was a multi-centre, randomised, double-blind, within-subject, placebo controlled Phase 2 study to investigate the safety and scar improvement efficacy of Juvista in 63 female subjects, aged 19 to 55, following bilateral breast augmentation surgery.

Each subject was administered 50ng or 200ng/100µL/linear cm intradermally along both margins of one breast wound immediately following surgery. 100µL/linear cm of placebo was administered to the other breast wound.

The primary endpoint of the trial was a visual analogue scale (VAS) score generated by an independent lay panel (to simulate customers) following review of scar photographs taken at 12 months post surgery.

### **About Renovo Group plc**

Renovo is a biopharmaceutical product company and is the world leader in scar reduction research and the development of drugs to reduce scarring.

Renovo has a portfolio of drugs which exploit different novel mechanisms of action to reduce scarring at multiple body sites and to accelerate healing. Juvista<sup>®</sup>, Renovo's lead drug for the reduction of scarring in the skin has been safely administered to over 1,500 human subjects and has reported statistical and clinical significance in seven Phase 2 efficacy trials.

Renovo announced in June 2007 that it had signed an exclusive licensing agreement with Shire plc to develop and commercialise Juvista. The agreement covers every country in the world except the European Union, the rights to which have been retained by Renovo. Under the terms of the deal Renovo has already received an initial payment of US\$125 million. Contingent on the successful development and commercialisation of Juvista Renovo will be eligible for further payments of up to \$700 million together with escalating royalties on sales.

Zestem<sup>®</sup>, Renovo's lead drug for the acceleration of wound healing in the skin, commenced Phase 3 clinical trials in December 2006. Prevascar<sup>™</sup> reported statistically significant Phase 2 efficacy data for the reduction of scarring in the skin in April 2007 and is additionally being investigated for enhancing regeneration of peripheral nerves following injury or trauma.

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For further information on Renovo please visit: [www.renovo.com](http://www.renovo.com)

### **About Shire plc**

Shire's strategic goal is to become the leading specialty biopharmaceutical company that focuses on meeting the needs of the specialist physician. Shire focuses its business on attention deficit and hyperactivity disorder (ADHD), human genetic therapies (HGT), gastrointestinal (GI) and renal diseases. The structure is sufficiently flexible to allow Shire to target new therapeutic areas to the extent opportunities arise through acquisitions. Shire's in-licensing, merger and acquisition efforts are focused on products in niche markets with strong intellectual property protection either in the US or Europe. Shire believes that a carefully selected portfolio of products with a strategically aligned and relatively small-scale sales force will deliver strong results.

For further information on Shire, please visit Shire's website: [www.shire.com](http://www.shire.com).