

**Ark's Kerraboot<sup>®</sup> effective in managing a wide range of ulcer types in the community – benefits over standard care shown.**

***Initial post-marketing study results***

**31 AUGUST 2004, London UK:** Ark Therapeutics Group plc today announces the preliminary results of its third clinical study of Kerraboot<sup>®</sup>, the Company's novel wound dressing device for the management of foot and leg ulcers. The study, comparing Kerraboot<sup>®</sup> with current standard care, met both primary and secondary study objectives, showing Kerraboot<sup>®</sup> to be effective in the management of diabetic foot and leg ulcers in primary care-based patients. Benefits demonstrated over standard care were reduced dressing time, ease of use and improvements in quality of life indicators. The full results of the study will be presented at the "Wounds UK" Conference in Harrogate, 15-17 November 2004.

Overall, the outcomes from this third study complement those seen in the previous two clinical studies. Taking the results of these three trials together, they show that Kerraboot<sup>®</sup> can be successfully used across all ulcer severities ranging from hospitalised cases with very severe ulcers being considered for leg amputation, through difficult out-patient cases to the milder cases being cared for at home.

Dr Mike Edmonds, Consultant Physician at Kings College Hospital, London led this multi-centre, randomised, open label study which evaluated the use of Kerraboot<sup>®</sup> compared with standard care dressings in the management of diabetic foot ulcers over a four week period. Five major UK wound care centres took part in the study.<sup>1</sup>

Over the study period, the overall healing profile of the Kerraboot<sup>®</sup> group showed greater improvements in granulation and reduced 'sloughing' even though these patients had worse ulcers to start with. Also, greater improvements were noted in pain reduction and stress indicators versus standard therapy. In comparison to standard dressings, Kerraboot<sup>®</sup> resulted in a 50% reduction in the time needed by nurses to change the dressing and all patients rapidly became nurse-independent, being able to change dressing themselves. In terms of acceptability, the healthcare workers and patients rated the Kerraboot<sup>®</sup> better for most parameters tested, notably ease of application and removal, convenience and improved patient mobility.

Dr Alan Boyd, Research and Development Director at Ark said: "We are pleased with these initial results and, combined with the outcomes from previous studies, we now have evidence to support the use of Kerraboot<sup>®</sup> across the range of ulcer types in both hospitalised and primary care-based patients. Kerraboot<sup>®</sup> has been shown to offer considerable healthcare and patient benefits over traditional ulcer and wound care approaches, including the potential for cost savings

in the management of these patients. We look forward to presenting the full study data at “Wounds UK” later this year.”

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<sup>1</sup> Kings College Hospital, London; Royal Bournemouth Hospital, Bournemouth; Manchester Royal Infirmary, Manchester; Tameside General Hospital, Ashton-Under-Lyme and Hope Hospital, Salford

**Notes to Editors**

**Kerraboot®**

Kerraboot® provides a new time-saving approach to the management of foot and leg ulcers in the form of an easy to apply, non-pressurised boot-like dressing. The product design incorporates a number of advanced medical device materials which generate a warm, moist environment for healing while facilitating the draining and isolation of exudates from the ulcerated area. Thus, substances such as matrix metalloproteases which can inhibit angiogenesis within the ulcer are reduced allowing natural growth factors, such as Vascular Endothelial Growth Factors (VEGF), to stimulate the re-granulation and healing of the affected area.

**Foot and Leg Ulcer Facts**

It is estimated that lower leg and foot ulceration affects 1% of the adult population in the developed world and is particularly prevalent amongst diabetics where ulcers can develop rapidly and are difficult to heal. Kerraboot® provides a new approach to their management in the form of a novel, non pressurized boot-like dressing device, which is simple and quick to use and pain free to change. Kerraboot®'s design incorporates a number of advanced medical device materials that generate a warm, moist environment for healing, while facilitating the draining and isolation of exudates, which inhibit angiogenesis, from the ulcer. This allows natural growth factors, such as Vascular Endothelial Growth Factors (VEGF), to stimulate healing.

**Ark Therapeutics Group plc**

Ark is an emerging healthcare group (the “Group”) with one marketed product and three further lead products in late stage clinical development. Capitalising on over ten years of research in vascular biology and gene-based medicine, Ark has a balanced product portfolio targeted at specific unmet clinical needs within vascular disease and cancer. These are large and growing markets, where opportunities exist for effective new products to generate significant revenues.

Ark’s products are sourced from related but largely non-dependent technologies within the Group and have been selected to enable them to be taken through development within the Company’s own means and to benefit from Orphan Drug Status and/or Fast Track Designation, as appropriate. This strategy has allowed the Group to retain greater value and greater control of clinical development timelines, and to mitigate the risks of dependency on any one particular programme or development partner. Ark has secured patents or has patent applications pending for all its lead products in principal pharmaceutical markets.

Ark has its origins in businesses established in the mid-1990s by Professor John Martin and Mr Stephen Barker of University College London and Professor Seppo Ylä-Herttuala of the AI Virtanen Institute at the University of Kuopio, Finland, all of whom continue to play leading roles in the Company’s research and development programmes.

This announcement includes “forward-looking statements” which include all statements other than statements of historical facts, including, without limitation, those regarding the Group’s financial position, business strategy, plans and objectives of management for future operations (including development plans and objectives relating to the Group’s products and services), and any statements preceded by, followed by or that include forward-looking terminology such as the words “targets”, “believes”, “estimates”, “expects”, “aims”, “intends”, “will”, “can”, “may”, “anticipates”, “would”, “should”, “could” or similar expressions or the negative thereof. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors beyond the Group’s control that could cause the actual results, performance or achievements of the Group to be materially different from future results, performance or achievements expressed or

implied by such forward-looking statements. Such forward-looking statements are based on numerous assumptions regarding the Group's present and future business strategies and the environment in which the Group will operate in the future. Among the important factors that could cause the Group's actual results, performance or achievements to differ materially from those in forward-looking statements include those relating to Ark's funding requirements, regulatory approvals, clinical trials, reliance on third parties, intellectual property, key personnel and other factors. These forward-looking statements speak only as at the date of this announcement. The Group expressly disclaims any obligation or undertaking to disseminate any updates or revisions to any forward-looking statements contained in this announcement to reflect any change in the Group's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based. As a result of these factors, prospective investors are cautioned not to rely on any forward-looking statement.