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Novuspharma SpA Announces Financial Results for the Three Months Ended 31 March 2003

Bresso, Italy, 14 May 2003 – Novuspharma SpA (Nuovo Mercato: NOV.MI), a biopharmaceutical company focused on cancer, today announces financial results for the three months ended 31 March 2003 and an update on R&D in the first quarter.

Highlights:

- Pivotal phase III trial continuing for pixantrone (BBR 2778) in indolent non-Hodgkin's lymphoma (NHL) in combination with Rituxan (rituximab).
- Results of a phase I/II trial for pixantrone in the BSHAP combination accepted for presentation at the International Society of Experimental Haematology, on July 5-8. A large phase II trial for the BSHAP regimen is due to start in Q3 2003.
- Results of a phase II study for BBR 3576 in patients with hormone refractory prostate cancer (HRPC) accepted for presentation at the American Society of Clinical Oncology (ASCO) on May 31 to June 3. A second phase II trial in combination with prednisone is due to start in Q3.
- Phase II trials for MT201 in a number of major solid tumour indications are due to start in 2003, with the first trial in early stage prostate cancer expected to begin in Q3.
- Dr. David Ebsworth appointed as a non-executive director in April.
- Net loss for the first three months of 2003 of €8.3 million (Q1 2002: €7.3 million). This increase reflects the advanced stage of our clinical programmes and is in line with projections.
- Cash balance at 31 March of €102.2 million (31 December 2002: €109.8 million).

Mr Silvano Spinelli, Chief Executive Officer, said:

“We have continued to progress our expanding clinical and pre-clinical pipeline while carefully controlling our resources. We look forward to announcing results from a phase II study for BBR 3576 in prostate cancer later this month and the start of a phase II programme for MT201 in Q3. The Company continues to be well financed to achieve its goals and considers all opportunities for maximising its potential.”

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For further information, please visit the Company's website at www.novuspharma.com.

CHIEF EXECUTIVE OFFICER'S REVIEW

FINANCIAL REVIEW

Revenues for the twelve months ended 31 March 2003 were €167,000 compared to €8,000 in 2002. Revenues in the period were mainly due to public grants supporting Novuspharma's research programmes.

Net loss for the period was €8.3 million compared with €7.3 million in 2002. This increase was in line with the Company's expectations and reflects the advanced stage of the products in clinical development, particularly the large-scale studies with pixantrone for NHL.

The Company's cash balance as of 31 March 2003 was €102.2 million (31 December 2002: €109.8 million), leaving Novuspharma well financed to achieve its goals in 2003 and beyond.

CLINICAL PROGRAMMES

Pixantrone

- A pivotal phase III trial is continuing for pixantrone in indolent NHL. Recruitment to this trial began in late 2002 and the study is designed to compare single agent rituximab, the current standard treatment, with a pixantrone/rituximab combination. This trial is expected to recruit around 800 patients in the US and Europe and its primary efficacy endpoint is time to disease progression.
- Novuspharma has received notification that the results of a phase I/II dose ranging trial for pixantrone in the BSHAP combination have been accepted for presentation at the International Society of Experimental Haematology, which is due to be held on July 5-8 in Paris. In this trial pixantrone was used in combination with cytarabine, methylprednisolone and cisplatin, in patients with relapsed aggressive NHL. This is a variant of the ESHAP regimen, which is commonly used in the treatment of aggressive NHL, where pixantrone replaces etoposide. The aim of this trial was to establish the appropriate dose of pixantrone to be used in this combination, as well as to evaluate the regimen's safety and activity profile. Preliminary results have shown a very promising number of complete responses, with several patients able to proceed to bone marrow transplant.
- A large phase II trial for pixantrone in the BSHAP combination is due to start in Q3. This trial will recruit 75 patients with relapsed aggressive NHL in the United States and will evaluate the efficacy of BSHAP, both as an induction regimen before bone marrow transplant and high dose chemotherapy and as a salvage therapy.

BBR 3576

- Novuspharma is due to present the results of a phase II trial for BBR 3576 in hormone refractory prostate cancer (HRPC) at the 2003 annual meeting of the American Society of Clinical Oncology (ASCO), which will be held on May 31 to June 3 in Chicago. In this trial, over 75 patients with HRPC were treated with single agent BBR 3576 (the majority of these patients had relapsed following previous chemotherapy treatment). Preliminary results from this trial show a promising number of responses, as assessed by a decrease in PSA (prostate specific antigen) a serum marker.
- A second phase II trial using BBR 3576 in combination with prednisone is due to start in Q3, which will enrol patients with HRPC that have not been previously treated with chemotherapy. Prednisone is a corticosteroid that is known to be highly synergistic with DNA intercalators, particularly mitoxantrone which is used in the treatment of HRPC (BBR 3576 also belongs to the DNA intercalator family of molecules). The regulatory strategy and possible pivotal trial designs for BBR 3576 in HRPC are currently under discussion and the BBR 3576 / prednisone combination may be used in a pivotal trial.

Pixantrone and BBR 3576 belong to a family of molecules known as DNA intercalators with improved efficacy and safety (see the editorial notes for a full explanation).

MT201

- Preparations are underway for a programme of phase II trials for MT201 in a number of major solid tumour indications. The first trial will be conducted in patients with early-stage prostate cancer and is due to open for recruitment in Q3. MT201 is a fully human antibody that targets the Ep-CAM antigen, which Novuspharma is co-developing with the German company Micromet. A phase I trial completed in 2002 revealed that MT201 has an excellent safety and tolerability profile, with appropriate pharmacokinetics.

Notes to Editors

Novuspharma SpA, based in Bresso, Milan, is a biopharmaceutical company focused on the discovery and development of innovative anti-cancer therapies. It has three products in clinical development and a dynamic research programme. Novuspharma was created in 1998 as a spin-off from Boehringer Mannheim and Hoffmann-La Roche, and has a proven track record in product development. Novuspharma makes use of a complete range of discovery and development platforms and focuses its specific expertise on the most critical part of the development process from the initial identification of leads to late clinical development stages as far as New Drug Application.

DNA intercalators with improved efficacy and safety. The most advanced products which Novuspharma has in clinical development belong to the DNA intercalator family of molecules. The currently marketed drugs from this class form one of the keystones of modern chemotherapy but suffer from the major drawback that they cause irreversible damage to heart muscle, which limits their use to a maximum cumulative dose within a patient's life-time. Novuspharma has used its expertise in medical chemistry to alter the structure of currently marketed DNA intercalators, in order to improve their safety and efficacy and specifically to reduce their cardiotoxicity.

Pixantrone (BBR 2778) and non-Hodgkin's Lymphoma. Pixantrone is a DNA intercalator with improved efficacy and safety which Novuspharma is developing for non-Hodgkin's lymphoma (NHL). NHL is caused by the abnormal proliferation of lymphocytes (immune system cells) and is estimated to affect 500,000 patients in the western world and Japan, expected to grow to over 680,000 by 2010 (source: Datamonitor). Pixantrone has produced encouraging results to date, both from pre-clinical studies and from clinical trials. In particular, in phase II trials in patients with advanced aggressive NHL, pixantrone achieved 5 complete responses (CRs) and 4 partial responses (PRs) out of 33 patients. Currently Novuspharma is conducting a pivotal phase III trial in relapsed indolent NHL. This trial is expected to recruit around 800 patients in the US and Europe and will compare the efficacy and safety of pixantrone, in combination with rituximab (Rituxan®) to rituximab alone, with time to disease progression as the primary efficacy endpoint.

BBR 3576 is a DNA intercalator with improved efficacy and safety which has shown its highest activity in solid tumours. BBR 3576 has produced encouraging results to date, both from preclinical studies and from clinical trials. In particular, preliminary phase II results in hormone refractory prostate cancer (HRPC) have shown a promising number of complete and partial responses. The phase II programme for BBR 3576 in HRPC is currently being expanded in preparation for a pivotal trial in this indication.

MT201 is a fully human antibody targeting the Ep-CAM antigen that Novuspharma is developing in collaboration with Micromet AG. The Ep-CAM antigen is a well validated clinical target which is present on the surface of the majority of carcinoma cells and therefore MT201 has the potential to be used in a wide range of solid tumours. In addition, the human nature of MT201 gives it low immunogenicity and should allow it to induce efficient elimination of tumour cells by interacting with the patient's immune system. Preliminary results from a phase I study in HRPC, revealed the product was well tolerated and had a good pharmacokinetic profile. Preparations are underway to start a number of phase II studies in solid tumours later this year.

Profit and Loss highlights

amounts in Euro/000	31/03/2003	31/03/2002
Revenues	167	8
R&D costs	(6,046)	(5,677)
Other operating costs	(1,763)	(1,658)
EBITDA	(7,642)	(7,327)
Depreciation, amortisation and write-downs	(1,230)	(1,188)
EBIT	(8,872)	(8,515)
Net financial income	606	1,209
Net loss for the period	(8,266)	(7,306)

Balance sheet highlights

amounts in Euro/000	31/03/2003	31/12/2002
Cash and cash equivalents	52,188	57,860
Marketable securities	50,003	51,982
Other current assets	9,916	11,001
Net intangible and tangible fixed assets	6,963	7,941
Total assets	119,070	128,784
Short-term liabilities	8,519	10,216
Long-term obligations	1,251	1,002
Net equity	109,300	117,566
Total liabilities and net equity	119,070	128,784