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Novuspharma SpA Announces Financial Results for the Twelve Months ended 31 December 2002

Bresso, Italy, 28 February 2003 – Novuspharma SpA (Nuovo Mercato: NOV.MI), a biopharmaceutical company focused on cancer, today announces financial results for the twelve months ended 31 December 2002 and an update on R&D in the fourth quarter.

Highlights:

- Pivotal phase III study underway for pixantrone (BBR 2778, INN name pending) in indolent non-Hodgkin's Lymphoma (NHL) in combination with Rituxan (rituximab).
- Encouraging preliminary results seen in all three phase I/II, dose-ranging trials for pixantrone in combination with other cytotoxic therapies, in both aggressive and indolent NHL. A large phase II trial in relapsed aggressive NHL due to start in Q2 2003.
- Phase I trial for pixantrone in multiple sclerosis due to start in 2003, following a presentation of the proposed trial design at the European Charcot Foundation meeting in Seville.
- Agreement signed with Micromet AG to co-develop MT201, a fully human antibody targeting the Ep-CAM molecule. The first of a series of phase II trials expected to start in the first half of 2003.
- Encouraging preliminary results seen with BBR 3576 in a phase II trial in hormone refractory prostate cancer (HRPC). The regulatory strategy and possible pivotal trial designs for BBR 3576 in HRPC are currently being evaluated, alongside an expansion of the phase II programme to include combination regimens.
- HIF-1? research programme expanded though a three-year collaboration with the US National Cancer Institute (NCI).
- Collaboration formed with Cephalon; several-fold increase in potency and selectivity of Cephalon's lead proteasome inhibitors achieved.
- Net loss for the full year 2002 of €32.1 million (full year 2001: €15.8 million). This increase reflects the advanced stage of our clinical programmes and is in line with projections.
- Cash balance at 31 December of €109.8 million (31 December 2001: €141.8 million).

Mr Silvano Spinelli, Chief Executive Officer, said:
"The Company made further important progress in 2002 including the start of a phase III trial on pixantrone and encouraging results from a number of phase I/II studies. We continued to work to broaden our technology and product base and to spread the risk for shareholders through our antibody agreement with Micromet, a lead optimisation collaboration with Cephalon and the expansion of a promising research programme with the US National Cancer Institute."

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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 December 2002 were €5.6 million compared to €1.6 million in 2001. Revenues in the period were mainly due to public grants supporting Novuspharma's research programmes.

Net loss for the period was €32.1 million compared with €15.8 million in 2001. 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 December 2002 was €109.8 million (31 December 2001: €141.8 million), leaving Novuspharma well financed to achieve its goals in 2003 and beyond.

CLINICAL PROGRAMMES

Pixantrone

- Recruitment for the phase III study in relapsed indolent NHL began in the second half of 2002. This study is comparing 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.
- Encouraging preliminary results have been obtained in the dose ranging trials for pixantrone in combination with other cytotoxic therapies. Recruitment has been completed in the phase I/II ESHAP variant trial, in aggressive NHL, with 20 patients enrolled. In this trial pixantrone is being combined with cisplatin and high doses of ara-c (the so called BSHAP combination regimen). A very high number of complete responses have been seen among the first 15 evaluable patients. A large phase II trial using the BSHAP regimen is expected to start in the second quarter of this year, recruiting up to 75 patients.
- Recruitment is ongoing in the phase I/II CHOP variant trial in aggressive NHL. In this trial pixantrone replaces doxorubicin in the CHOP combination, which represents the standard-of-care treatment in first-line aggressive NHL (i.e. pixantrone is being administered in combination with cyclophosphamide, vincristine and prednisone). To date there has been an encouraging number of responses among the first 12 evaluable patients.
- The first patients treated with the variant FND-R combination in indolent NHL have responded well, with most showing complete remission. In this trial, pixantrone replaces the DNA intercalator mitoxantrone in the FND-R combination, where it is being administered in combination with fludarabine, steroid and rituximab.
- The design of a planned phase I trial for pixantrone in multiple sclerosis was outlined at the European Charcot Foundation meeting in Seville. The development of pixantrone in this indication is supported by pre-clinical studies released earlier this year in which pixantrone displayed comparable activity to mitoxantrone, without the safety issues related to cardiotoxicity. Recruitment to this trial is due to start in 2003.

BBR 3576

- Recruitment in the phase II trial for BBR 3576 in hormone refractory prostate cancer (HRPC) has been completed, with 75 patients enrolled. Preliminary results have been encouraging with a promising number of complete and partial responses among the currently evaluable patients, as assessed by a decrease in PSA, a serum marker.
- Based on these encouraging results, BBR 3576 has been selected for full development in this indication. The regulatory strategy and possible pivotal trial designs are currently

being evaluated. A phase II trial in combination with prednisone is due to start in the first half of 2003. We expect this to be followed by a phase I/II trial in combination with docetaxel in the second half of this year.

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

MT201

- In September, Novuspharma entered into an agreement with Micromet AG to co-develop MT201, a fully human antibody targeting the Ep-CAM molecule, which has potential in a wide range of solid tumours.
- Preliminary results from the phase I study in hormone-refractory prostate cancer (HRPC) have shown that MT201 is well tolerated and has the appropriate pharmacokinetic profile.
- Preparations are underway to start a phase II trial in early stage prostate cancer in Q2, followed by further phase II trials in other solid tumour indications in the second half of 2003.

RESEARCH PROGRAMMES

Proteasome Inhibitors

- The collaboration with Cephalon, signed in May 2002, is progressing well. Lead optimisation to date has lead to a several-fold increase in the potency and selectivity of Cephalon's compounds on tumour cell lines and recent *in vivo* studies have shown a sustained, high level of proteasome inhibition.

Expansion of HIF-1? inhibitors project

- In September, Novuspharma expanded its research focused HIF-1? inhibitors, through a Cooperative Research and Development Agreement (CRADA) with the US National Cancer Institute (NCI). HIF-1? is a transcription factor known to play a role in regulating tumour cell survival, proliferation and angiogenesis (growth of new blood vessels into tumours).
- New laboratories have been established in Bresso, where a second programme of high-throughput screening will take place. Lead validation will continue on a number of more advanced compounds.

Notes to Editors

Novuspharma SpA (Bloomberg: NVUSF; Reuters: NOV.MI), 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 preclinical 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 immunogenity 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.

www.novuspharma.com

Profit and Loss highlights

Amounts in €uro/000	31/12/2002	31/12/2001
Revenues	**5,623**	**1,601**
R&D costs	- 25,332	- 13,865
Other operating costs	- 6,672	- 5,344
EBITDA	**- 26,381**	**- 17,608**
Depreciation, amortisation and write-downs	- 8,879	- 4,612
EBIT	**- 35,260**	**- 22,220**
Net financial income	3,199	6,452
Net loss for the year	**- 32,061**	**- 15,768**

Balance sheet highlights

Amounts in €uro/000	31/12/2002	31/12/2001
Net financial position	109,842	141,837
Other current assets	11,001	5,221
Net intangible and tangible fixed assets	7,941	10,382
Total assets	**128,784**	**157,440**
Short-term liabilities	10,216	6,988
Long-term obligations	1,002	825
Net equity	117,566	149,627
Total liabilities and net equity	**128,784**	**157,440**