SYNOPSIS OF RESEARCH REPORT [redacted] (PROTOCOL NO17754)

COMPANY: NAME OF FINISHED PRODUCT: NAME OF ACTIVE SUBSTANCE(S):	(FOR NATIONAL AUTHORITY USE ONLY)

TITLE OF THE STUDY / REPORT No. / DATE OF REPORT	Extension protocol for patients with Chronic Myelogenous Leukemia, Malignant Melanoma or Renal Cell Carcinoma that have responded to treatment with Pegylated-interferon α-2a or Roferon®-A in prior clinical studies. Report No. [redacted] / August, 2008.		
INVESTIGATORS / CENTERS AND COUNTRIES	[redacted], Bulgaria / [redacted], Canada / [redacted], India / [redacted], Russia / [redacted], Russia / [redacted], Russia / [redacted], South Africa / [redacted], Spain / [redacted], USA		
PUBLICATION (REFERENCE)	Not applicable		
PERIOD OF TRIAL	Jan 2004 to Jan 2008	CLINICAL PHASE	2/3
OBJECTIVES	• To allow patients who have responded to treatment with Pegylated-interferon α-2a (PEG-IFN) or Roferon®-A in prior clinical protocols the opportunity to continue with study drug. • To monitor safety in terms of serious adverse events (SAEs).		
STUDY DESIGN	This was an open-label extension study with a planned duration of 3 years.		
NUMBER OF SUBJECTS	9 subjects		
DIAGNOSIS AND MAIN CRITERIA FOR INCLUSION	Patients who completed study NO15753, NO15764, NO16006 or NO16007 and had responded to treatment at the end of the trial as defined in the parent protocol. Chronic myelogenous leukemia (CML) patients had to have a confirmed cytogenetic complete response within 2 months of entering this study. Malignant melanoma (MM) and renal cell carcinoma (RCC) patients had to have tumor assessments verifying stable or better response within 2 months of entering this study.		
TRIAL DRUG / STROKE (BATCH) No.	PEG-IFN / [redacted] (270 µg/mL), [redacted] (360 µg/mL) Roferon®-A / [redacted] (3 MIU/0.5 mL); [redacted] (6 MIU/0.5 mL); [redacted]		

SYNOPSIS OF RESEARCH REPORT [redacted] (PROTOCOL NO17754)

COMPANY: NAME OF FINISHED PRODUCT: NAME OF ACTIVE SUBSTANCE(S):	(FOR NATIONAL AUTHORITY USE ONLY)

	(9 MIU/0.5 mL)
DOSE / ROUTE / REGIMEN / DURATION	Patients were maintained on the PEG-IFN or Roferon®-A dose they were on at the time of transitioning from the parent protocol. PEG-IFN / subcutaneously / once weekly / 3 years Roferon®-A / subcutaneously / once daily / 3 years
REFERENCE DRUG / STROKE (BATCH) No.	Not applicable
CRITERIA FOR EVALUATION	
EFFICACY:	Tumor response was assessed every 6 months. For CML patients, the method of assessment could be limited to hematological evaluation. For MM and RCC patients, response was assessed using appropriate diagnostic techniques.
SAFETY:	Serious adverse events were monitored.
STATISTICAL METHODS	Results are presented descriptively.

SYNOPSIS OF RESEARCH REPORT [redacted]
(PROTOCOL NO17754)

COMPANY: NAME OF FINISHED PRODUCT: NAME OF ACTIVE SUBSTANCE(S):	(FOR NATIONAL AUTHORITY USE ONLY)

METHODOLOGY:

Patients received either PEG-IFN once weekly or Roferon®-A daily and had tumor response assessed every 6 months or when deemed necessary by the investigator. Patients with progressive disease were discontinued from the study. A safety follow-up visit was performed within 4 weeks after the discontinuation of study treatment.

STUDY POPULATION:

A total of 9 patients (7 males and 2 females) entered the study: 8 from study NO16006 and 1 from study NO16007 (page 7). Seven patients received PEG-IFN (270 µg, 4 patients; 360 µg, 1 patient; 450 µg, 2 patients) and two patients received Roferon®-A (3 MIU, 1 patient; 9 MIU, 1 patient). Four patients completed the study and 5 patients prematurely withdrew (page 8). Reasons for premature withdrawal included patient refusal to continue or withdrew consent (3 patients), disease remission (1 patient), and death due to an acute infection (1 patient).

EFFICACY RESULTS:

None of the patient's disease progressed during the study (page 9).

SAFETY RESULTS:

One patient had a serious adverse event and died during the study. Patient [redacted], a [redacted], [redacted] (page 11 and page 14). [redacted]

CONCLUSIONS:

Long-term treatment with PEG-IFN or Roferon-A was well tolerated.