The summary presented is based upon independent examination and these data should not be construed as demonstrating efficacy and safety of CV 247 since the product has not yet received regulatory approval.

**Summary of the outcome of the palliative study at St Francis Hospice**

*Does cv247 influence quality of life and malignant progression in patients with cancer who have completed all available conventional treatment?*

A total of 36 patients were recruited into this open prospective Phase II study, during which patients were expected to attend for a monthly clinical and quality of life assessment for a total of 6 months. The study was under the medical directorship of Dr R Taylor and 2 centres were involved, the Hospice of St Francis in Berkhamsted, and a private clinic in Harrow, Middlesex. All patients had a documented history of late stage progressive cancer, which in several cases, notably breast and prostate cancers had metastasized to involve typically the brain or bone. The range of cancers presenting was varied: breast (7), prostate (7), mesothelioma (5), ovarian (3), lung (3), rectal (2) and 1 each of cervical, Non-Hodgkins lymphoma, thymoma, fallopian, bladder, colonic, myeloma, pancreatic, and basal cell.

A total of 12 (33%) patients completed 6 months treatment with CV247, 3 of whom presented with breast cancer, 5 with prostate, and 1 each of the patients with mesothelioma, NH lymphoma, ovarian and thymoma. Seven of the 12 patients have continued treatment for more than 12 months. Withdrawals from treatment were usually after the first assessment (11 patients) and were often because the patient decided for a variety of reasons that treatment with CV247 was not their preferred treatment option. In 7 cases these were patients who presented to the private clinic, who were all highly motivated and were actively investigating a wide variety of alternative treatments available to them. Withdrawal of patients who attended the clinics at least twice was: withdrawal after 1 month (2), 2 months (6), 3 months (4) and 4 months (1).

The primary end-point for efficacy was Quality of Life based upon the utilization of a self scored, validated (EORTC) questionnaire. Of the 25 patients who continued after the initial assessment, 12 had no change (+/- 1) in their combined total global health and quality of life scores, 3 had decreased scores and 10 (40%) had an improvement. For the 12 patients who completed the 6 month study, the mean combined score at entry was 10.4 (range 6-14), and after 6 months, 11.3 (range 6-14). Only 1 of the 12 had a score that was worse after 6 months. No statistical analysis has been undertaken. Because of the variety of cancers presenting, clinical examinations and biomarker determinations were of very limited value. In addition the type of highly motivated patient typically presenting, especially at the private clinic, probably gave a false impression of their true health status, particularly on study entry.

There were no serious adverse events. A total of 6 patients withdrew due, at least in part, to the severity of adverse events experienced during the study. One patient withdrew due to a “feeling of bloatedness”, one due to constipation, 3 because of indigestion and one reported “feeling drowsy”. Only the cases of indigestion were considered to be possibly related to CV247.