STALWART

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Enrolment 2008

As we communicated previously, STALWART closed prematurely for patient enrolment on 30 June 2008 due to a low (one digit) enrolment rate over more than a 6-month period in late 2007/early 2008. This announcement increased the overall enrolment rate during May and June 2008 to a total of 51 participants, which was great.

STALWART Status and Future

STALWART opened in September 2005 and as of 30 June 2008, a total of 267 participants across 47 sites in 10 countries worldwide have been enrolled into the study.

Although the original enrolment goal of 480 patients could not be reached, valuable data has been collected in STALWART and with the enrolment of 267 participants, the study will still have an 80% power to detect an 80% CD4 cell difference between the treatment groups.

All study participants will be followed-up until the common closing date on 28 February 2009 - 32 weeks after the last patient was randomized. This will allow all participants to reach the primary study outcome at week 32. The unblinding of study data will take place at a closed meeting in Bangkok in March 2009 and study results will be shared with investigators and study participants during 2009.

Should you have any suggestions for additional tests, analyses or substudies that could be done with the specimens collected in STALWART you are encouraged to submit a brief concept sheet for review by the STALWART team.

Patient Letter

A patient letter (dated 30 May 2008) has been distributed recently to all sites informing about the closure of the study. The version approved by your Ethics Committee (EC) should be given to study participants **before** the study closes to follow up on 28 February 2009. Please document distribution of the letter in each patient's medical record as well as on the previously distributed signature list, which should be faxed back to CHIP once completed.

Regulatory Requirements

All regulatory documents must be kept current until your site is officially de-registered from the study. This includes e.g. Continuing/Annual Review, Federal Wide Assurance (FWA), FDA 1572, Pharmacy Plan, Site Information Form, Signature Log, CVs etc. The de-registration deadline for all sites is 30 June 2008. Since study activities such as data queries and data cleaning will continue until that date, every site must have a Continuing/Annual Review valid until 30 June 2009. We will contact sites where this needs to be renewed.

Investigator's Brochure

DAIDS Regulatory Compliance Centre has recently informed that Novartis Pharmaceuticals has issued a new Investigator's Brochure (IB) for Proleukin/Aldesleukin (IL-2). As you are aware, Novartis acquired Chiron, the previous manufacturer of IL-2, in 2006. You will soon receive this new IB together with an explanatory letter. Please review the IB and submit it to your Ethics Committee (EC), thank you.

Important Points and Upcoming Deadlines

- **Data quality:** Please ensure accurate and complete data collection and submission in a timely manner as well as reporting of clinical endpoints and events upon site awareness
- **Week 32:** This study visit is **crucial for every STALWART study participant** since the **primary study outcome** is collected at week 32. Hence, please **ensure to meet and report this Week 32 study visit for all your study participants within the required visit window.** Thank you.
- **31 January 2009:** Last IL-2 cycle must be completed. Start cycles no less than 6 days prior to 31 January 2009.
  Of note: All Expedited Adverse Events (EAE) must be reported up to 8 weeks after the last dose of IL-2 is taken, even if the EAE occurs after 28 February 2009.
- **28 February 2009:** Last day for any follow-up visit. **Study visits where the anniversary date** (estimated date in the middle of a visit window) **is on or before 28 February 2009 are required study visits.** Please plan ahead to ensure no required study visits are lost. Site specific required visits are also available at the INSIGHT website (http://insight.ccbr.umn.edu/).
- **15 March 2009:** All Week 32 queries must be resolved
- **31 March 2009:** All blood specimens must be received at CHIP. Please make sure to label the cryovials correctly. Detailed instructions can be found in the Laboratory Manual.
- **30 April 2009:** All queries must be resolved

Next Meeting

The next INSIGHT/STALWART joint scientific session for investigators has been scheduled for Montreal, Canada, on 7 February 2009, in conjunction with the 16th Conference on Retroviruses and Opportunistic Infections (CROI). Details are forthcoming.

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