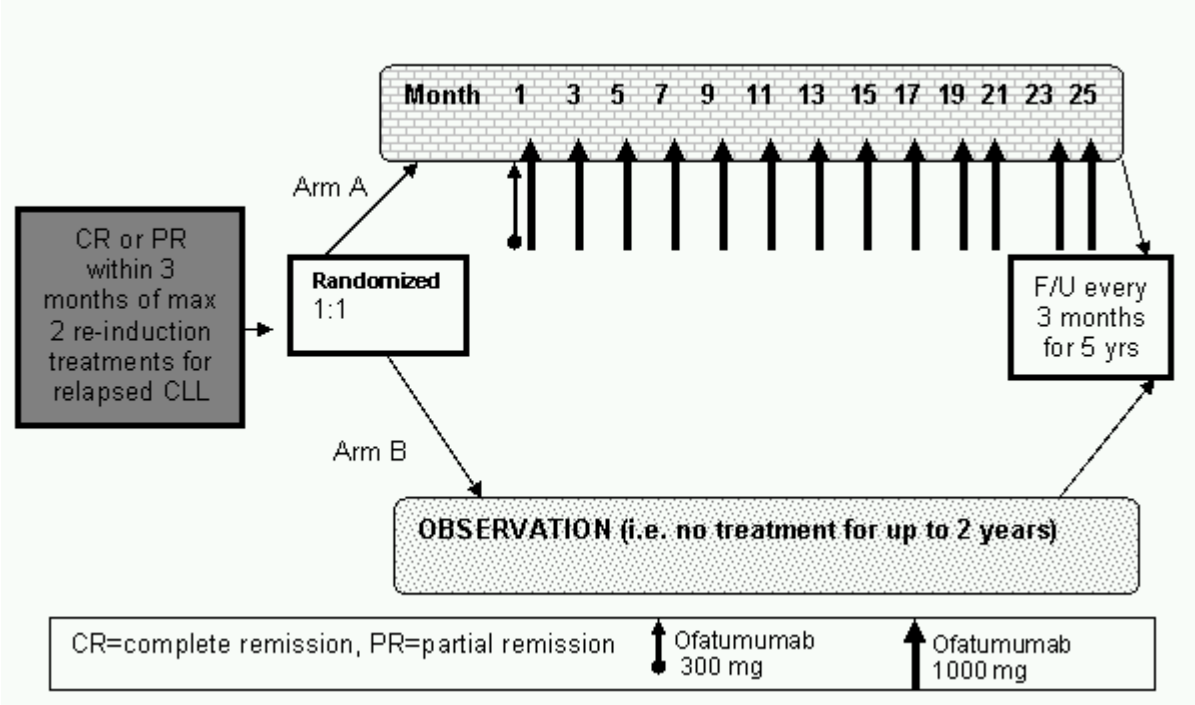
Hovon 101 PROLONG



Inclusion Criteria

Subjects eligible for enrollment in the study must meet all of the following criteria:

1. Adults with documented diagnosis of CLL based on the modified IWCLL updated NCI-WG guidelines [Hallek, 2008]

2. At least PR according to the revised 2008 NCI-WG CLL criteria within 3 months of the response assessment after the last dose of 2nd/3rd line treatment

3. The anti-leukemic treatment before study entry should have been for at least 3 months or 3 cycles

4. ECOG Performance Status of 0-2

5. Signed written informed consent prior to performing any study-specific procedures

Exclusion Criteria

Subjects meeting any of the following criteria must not be enrolled in the study:

1. Known primary or secondary fludarabine-refractory subjects, defined as treatment failure (failure to achieve a CR or PR) or disease progression within 6 months [Hallek, 2008]

2. Prior maintenance therapy

3. Known transformation of CLL (e.g. Richter's transformation), prolymphocytic leukemia (PLL), or CNS involvement of CLL

4. Active Autoimmune Hemolytic Anemia (AIHA) requiring treatment except if in the opinion of the investigator it is thought not to affect the subject's safety, the conduct of the study or the interpretation of the data

5. Previous autologous or allogeneic stem cell transplantation

6. Chronic or current active infectious disease requiring systemic antibiotics, antifungal, or antiviral treatment such as, but not limited to, chronic renal infection, chronic chest infection with bronchiectasis, tuberculosis and active Hepatitis B or C (Positive serology for Hepatitis B (HB) defined as a positive test for HBsAg. In addition, if negative for HBsAg but HBcAb positive (regardless of HBsAb status), a HBV DNA test will be performed and if positive the subject will be excluded*.)

7. Other past or current malignancy (with the exception of basal cell carcinoma of the skin or in situ carcinoma of the cervix or breast) unless the tumor was successfully treated with curative intent at least 2 years prior to trial entry except if in the opinion of the investigator it is thought not to affect the subject's safety, the conduct of the study or the interpretation of the data

8. Clinically significant cardiac disease including unstable angina, acute myocardial infarction within 6 months prior to screening, congestive heart failure, and arrhythmia requiring therapy, with the exception of extra systoles or minor conduction abnormalities except if in the opinion of the investigator it is thought not to affect the subject's safety, the conduct of the study or the interpretation of the data

9. History of significant cerebrovascular disease or event with symptoms or sequelae

10. Significant concurrent, uncontrolled medical condition that in the opinion of the investigator contraindicates participation in this study

11. Other anti-leukemic use of medications including glucocorticoids

12. Known HIV positive

13. Screening laboratory values:

• Platelets<50 x 10^9/L

• Neutrophils<1.0 x 10^9/L

• Creatinine > 1.5 times upper normal limit (unless normal creatinine clearance)

• Total bilirubin > 1.5 times upper normal limit (unless due to liver involvement of CLL or Gilbert's syndrome)

• Alanine Aminotransferase (ALT) > 2.5 times upper normal limit (unless due to liver involvement of CLL)

• Alkaline phosphatase > 2.5 times upper normal limit

14. Known or suspected hypersensitivity to ofatumumab that in the opinion of the investigator or medical monitor contraindicates study participation

15. Subjects who have received treatment with any non-marketed drug substance or experimental therapy within 5-terminal half-lives or 4 weeks whichever is longer prior to first dose of study medication or currently participating in any other interventional clinical study *Note: Participation in any other interventional clinical study after disease progression during post PD follow-up is permitted*

16. Lactating women, women with a positive pregnancy test at Visit 1 or women (of childbearing potential) as well as men with partners of childbearing potential, who are not willing to use adequate contraception from study start through one year following last ofatumumab dose. Adequate contraception is defined as abstinence, oral hormonal birth control, implants of levonorgestrel, estrogenic vaginal ring, percutaneous contraceptive patches, intrauterine device, and male partner sterilization if male partner is sole partner for that subject. For females in the USA, the use of a double barrier method is also considered adequate (condom or occlusive cap plus spermicidal agent).
* If HBV DNA is negative, subject may be included but must undergo HBV DNA monitoring (see Section 6.3.4). Prophylactic antiviral therapy may be initiated at the discretion of the investigator.