Pre-screening Checklist

Please use the following checklist to review preliminary patient eligibility for the SBT777101-01 trial.

Note: This document is not considered source documentation. Refer to the full list of criteria in the protocol to ensure eligibility.

KEY INCLUSION CRITERIA

If the status is *yes* to the following criteria, the patient may be eligible for the trial.

	YES	NO	NOT SURE*
A. Age ≥ 18 and ≤ 70 at time of signing ICF	☐	☐	☐
B. Body mass index (BMI) ≤ 35 kg/m^2	☐	☐	☐
C. Adult-onset RA (as per 2010 ACR/EULAR classification criteria)	☐	☐	☐
D. Moderate-to-severe active disease (as per DAS28 ≥3.2, calculated using CRP)	☐	☐	☐
E. Clinical and/or ultrasound evidence of synovitis	☐	☐	☐
F. At least 1 joint that can be used for synovial biopsy	☐	☐	☐
G. Willing to undergo synovial biopsy	☐	☐	☐
H. Inadequate response to or were unable to tolerate prior treatment with available therapies, including at least 3 prior b/tsDMARDs with differing mechanisms of action • An inadequate response is determined by the treating physician and may be based on RA that is difficult to treat and continued disease activity as measured by ≥4/28 tender and swollen joints, DAS28≥3.2, inability to taper corticosteroids to 7.5 mg or lower, or other appropriate measures, generally after 3 months of therapy on the recommended therapeutic dose	☐	☐	☐
I. Doses of RA medications (or biosimilars) have been stable for 30 days prior to Screening • For patients on rituximab, doses must have been stable for 90 days prior to Screening	☐	☐	☐
J. Willing to discontinue estrogen replacement therapy for at least 1 week or 5 half-lives prior to study treatment (if applicable)	☐	☐	☐
K. Willing to adhere to protocol requirements (including but not limited to having a trial companion, staying near the study site for 28 days, etc.)	☐	☐	☐

*Requires further site review

NOTES:

SONOMA BIOTHERAPEUTICS

Continued on reverse

KEY EXCLUSION CRITERIA

If the status is *yes* to the following criteria, the patient may NOT be eligible for the trial.

	YES	NO	NOT SURE*
A. History of or current inflammatory joint disease other than RA or other autoimmune or inflammatory disease that may confound clinical assessments or increase subject risk in the trial	☐	☐	☐
B. Major surgery (including joint surgery) within 12 weeks prior to Screening or planned within 12 months of trial cell therapy dosing	☐	☐	☐
C. Prior treatment with cell or gene therapy	☐	☐	☐
D. Intra-articular glucocorticoids within 90 days of Screening	☐	☐	☐
E. Leflunomide (without chelation) within 8 weeks of Screening	☐	☐	☐
F. Abatacept within 90 days of Screening	☐	☐	☐
G. Oral antibiotics/anti-infectives within 2 weeks of Screening	☐	☐	☐
H. Infection requiring hospitalization or treatment with IV antibiotics within 4 weeks of Screening	☐	☐	☐
I. Any medical or psychological condition that could interfere with the conduct of the trial or confound the interpretation of the trial results	☐	☐	☐
J. History of malignancy within 5 years	☐	☐	☐

*Requires further site review

NOTES: