Dermatology Practical & Conceptual

Supplementary File

Table S1. Inclusion and exclusion criteria of Managed Access Program (MAP) Cohort Treatment Plan CAIN457M2002M to provide access to Secukinumab for adult patients with Hidradenitis Suppurativa (HS).

Inclusion Criteria
Patients eligible for inclusion in this Treatment Plan have to meet all of the following criteria: 1. Adult male and female patients (≥ 18 years) who are able and willing to provide written informed consent prior to enrolling in the cohort. 2. HS diagnosis for ≥ 6 months (defined as onset of HS with supporting documentation) 3. Patients with moderate to severe HS defined as: • A total of at least 5 inflammatory lesions, i.e., abscesses and/or inflammatory nodules AND • Inflammatory lesions should affect at least 2 distinct anatomic areas 4. Not eligible or able to enroll in a clinical trial or no relevant clinical trials available
Exclusion Criteria
1. Total fistulae count ≥ 20 at baseline. 2. Active ongoing inflammatory diseases other than HS that require treatment with prohibited medications (prohibited medication: the use of live vaccines within 6 weeks prior to drug use until the end of administration). 3. Underlying conditions (including, but not limited to metabolic, hematologic, renal, hepatic, pulmonary, neurologic, endocrine, cardiac, infectious or gastrointestinal disorders, including history of inflammatory bowel disease) which in the opinion of the treating physician significantly immunocompromises the patient and/or places the patient at unacceptable risk for receiving an anti-IL-17A immunomodulatory therapy. 4. Current severe progressive or uncontrolled diseases which renders the patient unsuitable for the managed access program or puts the patient at increased risk, including any medical or psychiatric condition which, in the treating physician's opinion, would preclude the participant from adhering to the treatment plan. 5. Use or planned use of live vaccines within 6 weeks prior to drug use until the end of administration). 6. History of hypersensitivity to any of the secukinumab constituents. 7. History of chronic or recurrent systemic infections or active systemic infections during the last two weeks (exception: common cold) prior to the access request. 8. Evidence of tuberculosis infection as defined by a positive QuantiFERON® TB-Gold test (QFT) at the time of requesting access. Patients with a positive or indeterminate QFTtest may get access if a full tuberculosis work-up (according to local practice/guidelines) completed within 12 weeks prior to randomization, establishes conclusively that the patient has no evidence of active tuberculosis. Patients who test positive for latent TB per work-up may get access if sufficient treatment has been initiated according to local routine clinical practice/guidelines and was completed at least four weeks prior to the access request. 9. Medical history of infection with human immunodeficiency virus (HIV), hepatitis B or C prior to access request, except for hepatitis C successfully treated and cured. 10. History of lymphoproliferative disease or any known malignancy or history of malignancy of any organ system treated or untreated within the past 5 years, regardless of whether there is evidence of local recurrence or metastases (except for skin Bowen's disease, or basal cell carcinoma or actinic keratoses that have been treated with no evidence of recurrence in the past 12 weeks; carcinoma in situ of the cervix or non-invasive malignant colon polyps that have been removed). 11. History or evidence of ongoing alcohol or drug abuse, which in the opinion of the physician will prevent the patient from adhering to the treatment plan. 12. Pregnant or lactating women.

Table S1 continues

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13. Women of childbearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using methods of contraception during the entire duration of the treatment or longer if required by locally approved prescribing information (e.g., in European Union (EU) 20 weeks). Contraception methods include:
    - Total abstinence when this is in line with the preferred and usual lifestyle of the patient. Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception.
    - Female sterilization (have had surgical bilateral oophorectomy with or without hysterectomy), total hysterectomy, or bilateral tubal ligation at least six weeks prior to the access request. In case of oophorectomy alone, only when the reproductive status of the woman has been confirmed by follow-up hormone level assessment.
    - Male sterilization (at least 6 months prior to screening). The vasectomized male partner should be the sole partner for that patient.
    - Barrier methods of contraception: Condom or Occlusive cap (diaphragm or cervical/vault caps). For United Kingdom: with spermicidal foam/gel/film/cream/vaginal suppository.
    - Use of oral (estrogen and progesterone), injected or implanted hormonal methods of contraception or other forms of hormonal contraception that have comparable efficacy (failure rate <1%), for example hormone vaginal ring or transdermal hormone contraception or placement of an intrauterine device (IUD) or intrauterine system (IUS). In case of use of oral contraception, women should have been stable on the same pill for a minimum of 3 months before taking secukinumab. In case local regulations deviate from the contraception methods listed above, local regulations apply and will be described in the informed consent template. Note: Women are considered post-menopausal and not of childbearing potential if they have had 12 months of natural (spontaneous) amenorrhea with an appropriate clinical profile (e.g., age appropriate, history of vasomotor symptoms) or have had surgical bilateral oophorectomy (with or without hysterectomy), total hysterectomy or bilateral tubal ligation at least six weeks prior to enrollment. In the case of oophorectomy alone, only when their productive status of the woman has been confirmed by follow-up hormone level assessment is she considered not of childbearing potential.

Table S2. p values for the univariate analyses between different endpoints and demographic characteristics of patients.

	Week																			
	HiSCR[(a)]					IHS4-55[(a)]					Mean change in AN count from baseline[(b)]					NRS30[(a)]				
	4	8	16	32	48	4	8	16	32	48	4	8	16	32	48	4	8	16	32	48
Sex	0.779	1	1	1	1	1	1	1	1	1	0.70	0.37	0.56	0.25	0.58	1	1	1	1	1
Age	1	1	1	1	1	1	1	1	1	1	0.31	0.11	0.41	0.63	0.11	1	1	1	1	1
Onset	1	1	1	1	1	1	1	1	1	1	0.15	0.12	0.15	0.31	0.51	1	1	1	1	1
Family history	1	1	1	1	1	1	1	1	1	1	0.37	0.21	0.16	0.52	0.13	1	1	1	1	1
BMI	1	1	1	1	1	1	1	1	1	1	0.28	0.16	0.79	0.41	0.08	1	1	1	1	1
Smoking habit	1	1	1	1	1	1	1	1	1	1	0.39	0.95	0.19	0.09	0.12	1	1	1	1	1
Prior I&D	1	1	1	1	1	1	1	1	1	1	0.19	0.93	0.79	0.65	0.07	1	1	1	1	1

BMI, body mass index; HiSCR, Hidradenitis Suppurativa Clinical Response; IHS4-55, a 55% reduction in the International Hidradenitis Suppurativa Severity Score System, AN, abscess and nodule count; NRS30, a 30% or more reduction and reduction of two units or more from baseline in Patient's Global Assessment of Skin Pain on a continuous numeric rating scale; I&D, incision & drainage; [(a)] Logistic regression analysis; [(b)] simple linear regression analysis