A Phase 3, Multi-center, Open-label Continuation Study in Moderate to Severe Chronic Plaque Psoriasis Subjects who Completed a Preceding Psoriasis Study With ABT-874

Published: 20-11-2008
Last updated: 05-05-2024

To assess the long-term safety, tolerability and efficacy of ABT-874 in adults who have either completed or have demonstrated a loss of response (as defined in the original ABT-874 protocol) to treatment in a preceding ABT-874 study in the treatment...

Ethical review	Not approved
Status	Will not start
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON32696

Source
ToetsingOnline

Brief title
ABT-874 Open Label Study M10-016

Condition

- Epidermal and dermal conditions

Synonym
chronic plaque sporiasis

Research involving
Human

Sponsors and support

Primary sponsor: Abbott
Source(s) of monetary or material Support: Farmaceutisch bedrijf: Abbott GmbH & Co.K.G.

Intervention

Keyword: Chronic, Plaque, Psoriasis, Severe

Outcome measures

Primary outcome

Efficacy, safety and quality of life parameters to be evaluated include the

6-point Physicians Global Assessment (PGA), Psoriasis Area and Severity Index

(PASI) and Patient's Global Assessment of Psoriasis-Severity.

Secondary outcome

n.v.t.

Study description

Background summary

Psoriasis is a chronic immunologic disease characterized by marked inflammation and
thickening of the epidermis that results in thick, scaly plaques involving the skin. It
affects 1-3% of the general population, with the highest disease prevalence in North America and Europe.1 Psoriasis equally affects men and women, with peak onset
of symptoms in young adults and again in the mid 50's.

Psoriasis may be classified according to morphologic and clinical presentation: plaque
psoriasis, guttate psoriasis, erythrodermic psoriasis, generalized pustular and localized

pustular psoriasis, and inverse or intertriginous psoriasis. Plaque psoriasis is the most
common form seen in 75-80% of psoriasis patients.

Treatment depends on the extent and severity of disease. Topical corticosteroids are
commonly used for mild to moderate cases. Other topical medications include keratolytic
agents, anthralin, coal tar, vitamin D analogs, and retinoids.5 For more widespread
disease, phototherapy (ultraviolet B [UVB] or ultraviolet A and psoralen [PUVA]) is
commonly used. Systemic therapy, including methotrexate (MTX), cyclosporine and synthetic retinoids are often effective in patients with moderate or severe disease.

Study objective

To assess the long-term safety, tolerability and efficacy of ABT-874 in adults who have either completed or have demonstrated a loss of response (as defined in the original ABT-874 protocol) to treatment in a preceding ABT-874 study in the treatment of subjects with moderate to severe chronic plaque psoriasis.

Study design

Methodology:
This is a Phase 3, multi-center, open-label extension study designed to describe the safety, tolerability, and efficacy of long-term administration of the human monoclonal antibody against IL-12 in subjects with moderate to severe chronic plaque psoriasis.

Intervention

Open lable Study in which patients will be treated with 100 mg ABT-874 through 160 weeks

Study burden and risks

More than 475subjects participating in Phase II clinical trials have ben treated with ABT-874. The majority of side effects experienced following administration of ABT-874 were mild and moderate in severity.
The most common side effects after administration of ABT-874 were mild and moderate: headache, nausea, worsening of symptoms of rheumatoid arthritis and the common cold and infections as nasopharyngitis (inflammation of the nose and throat) amd upper respiratory tract infections, paraesthesia, pain in an extremity, hypoesthesia, diarrhea, back pain, dizziness, depression and relapse

of multiple sclerosis.

Serious adverse events have been observed with ABT-874 but have been uncommon. Serious adverse events reported in more than one patient include: intervertebral disc degeneration, headache, vomiting, injury, and multiple sclerosis relapse or multiple sclerosis (in subjects enrolled in multiple sclerosis study with diagnosis of multiple sclerosis).

The most common side effects at the injection side: redness, itching, bruising, pain and/or irritation.Most injection side reactions were mild and usually went away within a few hours to a few days.

Contacts

Public
Abbott

Siriusdreef 51
2132 WT Hoofddorp
Nederland
Scientific
Abbott

Siriusdreef 51
2132 WT Hoofddorp
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Subjects who participated in prior ABT-874 Phase 2 (protocol M05-736) or Phase 3 studies (protocols M06-890, M10-255, M10-014 and M10-315) and who did not prematurely discontinue any previous ABT-874 study (other than protocol required discontinuation due to loss of response as defined in the original ABT-874 protocol).
2. Males and females * 18 years of age.
3. Women are eligible to participate in the study if they meet one of the following criteria:
• Women of childbearing potential must undergo monthly pregnancy testing during the study and agree to use two of the following methods of contraception throughout the study and for 60 days after the last dose of study drug:
- Oral contraceptives;
- Transdermal contraceptives;
- Injectable or implantable methods;
- Intrauterine devices; and
- Barrier methods (diaphragm with spermicide, condom with spermicide).
Subjects using oral or parenteral forms of contraceptives must have been practicing birth control for at least three months prior to study drug administration.
• Women who are postmenopausal (for at least one year), sterile, or hysterectomized;
• Women who have undergone tubal ligation will be required to undergo monthly pregnancy testing during the duration of the study and agree to use a second form of contraception which includes:
- Oral contraceptives;
- Transdermal contraceptives;
- Injectable or implantable methods;
- Intrauterine devices; and
- Barrier methods (diaphragm with spermicide, or condom with spermicide);
• Sexual abstinence practiced throughout the study, defined as total abstinence from sexual intercourse, is considered an adequate form of contraception (agreement to comply with sexual abstinence must be recorded in the source document and must be discussed with the medical monitor).
4. Subject is judged to be in good general health as determined by the principal investigator based upon the results of medical history, laboratory profile, and physical examination.
5. Able and willing to give written informed consent and to comply with the requirements of this study protocol.

Exclusion criteria

1. Subjects who prematurely discontinued in any preceding psoriasis study with ABT-874 (other than protocol required discontinuation due to loss of response as defined in the original ABT-874 protocol).
2. Diagnosis of erythrodermic psoriasis, generalized or localized pustular psoriasis, medication- induced or medication-exacerbated psoriasis, or new onset guttate psoriasis.
3. Diagnosis of other active skin diseases or skin infections (bacterial, fungal, or viral) that

may interfere with evaluation of psoriasis.
4. History of an allergic reaction or significant sensitivity to constituents of study drug.
5. Subject that must use topical therapies for the treatment of psoriasis such as corticosteroids, vitamin D analogs, or retinoids during the study. Subjects are allowed to use:
• Shampoos that contain no corticosteroid,
• Bland (without beta or alpha hydroxy acids) emollients,
• Low potency (Class VI or Class VII) topical corticosteroids on the palms, soles, face, inframammary area, and groin only.
6. Cannot avoid UVB phototherapy during the study.
7. Cannot avoid PUVA phototherapy during the study.
8. Subject requires systemic therapies known to improve psoriasis, other than study drug, during the study
9. Subject is taking or requires oral or injectable corticosteroids during the study. Inhaled corticosteroids for stable medical conditions are allowed.
10. Poorly controlled medical condition, such as uncontrolled diabetes with documented history of recurrent infections, unstable ischemic heart disease, congestive heart failure, recent cerebrovascular accidents and any other condition which, in the opinion of the investigator, and/ or the medical monitor would put the subject at risk by participation in the study.
11. Subject has infection or risk factors for severe infections, for example:
• Excessive immunosuppression or other factors associated with it, including human immunodeficiency virus (HIV) infection.
• Severe, recurrent, or persistent infections such as Hepatitis B or C;
• Active tuberculous disease;
• Subject will require vaccination with a live viral agent during study.
12. History of malignancies other than successfully treated basal cell carcinoma or cervical carcinoma in situ;
13. History of major immunologic reaction (such as serum sickness or anaphylactoid reaction) to an Immunoglobulin G (IgG) containing agent (such as IV gamma globulin, a fusion protein, or monoclonal antibody).
14. Female subject who is pregnant or breast-feeding or considering becoming pregnant during the study or for 60 days after study completion;
15. Recent history of substance abuse or psychiatric illness that could preclude compliance with the protocol;
16. For any reason, subject is considered by the investigator and/or the medical monitor to be an unsuitable candidate to receive ABT-874.

Study design

Design

Study phase:	3
Study type:	Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	geen
Generic name:	geen

Ethics review

Approved WMO Date:	20-11-2008
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-12-2008
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Not approved Date:	03-02-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2007-005955-40-NL
CCMO	NL25466.091.08