[0005] The dermal papillae have a rich blood supply, which can make it easier to modulate with orally administered compositions (e.g., drugs, ingredients, supplements, etc.). As such, an oral composition that increases SULT1A1 enzyme in dermal papillae, dermal sheath, or outer root sheath of hair follicles and subsequently increases the response to minoxidil (which can be oral or topological) for the treatment of hair loss would be advantageous.

[0006] Prior to this present disclosure, it was not known as to whether an oral form of an alkalizing agent would be able induce the SULT1A1 enzyme in the scalp tissue. In addition, as it is known that patients chronically using large dosages of an oral alkalizing agent could develop metabolic alkalosis and other disorders, the negative effects of an oral form of an alkalizing agent were not know. The inventor has conducted a study to test these effects, the result of which are the basis of the innovations disclosed herein.

SUMMARY

[0007] Examples relate to compositions and methods for the treatment of hair loss, which can include treatment of alopecia, via an application of a composition including an alkalizing agent and/or a sulfotransferase enzyme. The composition can be formulated to be an orally administered composition. In some examples, the composition is used to increase the response of minoxidil.

[0008] In one aspect, the present disclosure refers to a composition for improving, increasing, or enhancing minoxidil response of a subject suffering from alopecia. The composition can include an alkalizing agent and a sulfotransferase enzyme.

[0009] In some examples, the composition can be formulated as a topological composition, an oral composition, an injectable composition, or a transdermal composition; and/or the composition can be formulated as a drug, a nutritional supplement, or a cosmetic.

[0010] In some examples, the composition can include minoxidil.

[0011] In some examples, the composition can include minoxidil. The composition can be formulated as a topological composition, an oral composition, an injectable composition, or a transdermal composition.

[0012] In some examples, the alkalizing agent can include one or more of a bicarbonate, citrate, a loop diuretic, MOPS, BES, TES, HEPES, DIPSO, TAPSO,

Acetamidoglycine, POPSO, HEPPSO, HEPPS, Tricine, Tris (tromethamine), Glycinamide, Glycylglycine, or Bicine, TAPS.

[0013] In some examples, the sulfotransferase enzyme can include a human sulfotransferase enzyme and/or a non-human sulfotransferase enzyme.

[0014] In some examples, the sulfotransferase enzyme can include one or more of a carbohydrate sulfotransferase, a galactose-3-O-sulfotransferase, a heparan sulfate 2-O-sulfotransferase, a heparan sulfate 3-O-sulfotransferase, a heparan sulfate 6-O-sulfotransferase, a N-deacetylase/N-sulfotransferase, a tyrosylprotein sulfotransferase, an uronyl-2-sulfotransferase, an estrone sulfotransferase, a chondroitin 4-sulfotransferase, SULT1A1, SULT1A2, SULT1A3, SULT1A4, SULT1B1, SULT1C2, SULT1C3, SULT1C4, SULT1D1P, SULT1E1, SULT2A1, SULT2B1, SULT4A1, or SULT6B1.

[0015] In some examples, the composition can contain natural levels or extracts of minoxidil sulfotransferase enzymes, natural levels or extracts of phenol sulfotransferase enzymes, and/or natural levels or extracts of sulfotransferase enzymes derived from Populus trichocarpa, Populus x canescens, Salix sp., Arabidopsis thaliana, silver poplar (Populus alba), Simon's poplar (Populus simonii), S. purpurea, P. tremuloides, I. polycarpa, P. nigra, Oryza sativa, Salicaceae family, Poplars (Populus sp.), Idesia polycarpa - Japanese orange cherry, Potato (Solanum tuberosum), Cabbage (Brassica rapa), Populus trichocarpa (Black cottonwood), Salix Sp. (Willow tree), Cotton (Gossypium), Olea europaea L, Brassica napus, Apium graveolens, brassica oleracea, Saccharina japonica, Solanum tuberosum, and/or Black cottonwood. The natural levels or extracts of minoxidil sulfotransferase enzymes, phenol sulfotransferase enzymes, and/or sulfotransferase enzymes is/are present in amounts ranging from 1%-100% by weight.

[0016] In some examples, the sulfotransferase enzyme can includeOeST1.

[0016a] In another aspect, there is provided a use of a composition comprising an alkalizing agent and a sulfotransferase enzyme in the manufacture of a medicament for improving, increasing, or enhancing minoxidil response of a subject suffering from alopecia.

[0017] An example can relate to a method for improving, increasing, or enhancing minoxidil response of a subject suffering from alopecia. The method can involve administering a composition comprising an alkalizing agent and a sulfotransferase enzyme to a subject suffering from alopecia.

[0018] In some examples, administering the composition can involve administering the composition topologically, orally, via injection, or transdermally; and/or administering the composition as a drug, a nutritional supplement, or a cosmetic.

[0019] In some examples, the method can involve administering the composition before, during, and/or after administration of minoxidil.

[0020] In some examples, the composition can include minoxidil.

[0021] In some examples, the alkalizing agent can include one or more of a bicarbonate, citrate, a loop diuretic, MOPS, BES, TES, HEPES, DIPSO, TAPSO, Acetamidoglycine, POPSO, HEPPSO, HEPPS, Tricine, Tris (tromethamine), Glycinamide, Glycylglycine, or Bicine, TAPS.

[0022] In some examples, the sulfotransferase enzyme can include a human sulfotransferase enzyme and/or a non-human sulfotransferase enzyme.

[0023] In some examples, the sulfotransferase enzyme can include one or more of a carbohydrate sulfotransferase, a galactose-3-O-sulfotransferase, a heparan sulfate 2-O-sulfotransferase, a heparan sulfate 3-O-sulfotransferase, a heparan sulfate 6-O-sulfotransferase, a N-deacetylase/N-sulfotransferase, a tyrosylprotein sulfotransferase, an uronyl-2-sulfotransferase, an estrone sulfotransferase, a chondroitin 4-sulfotransferase, SULT1A1, SULT1A2, SULT1A3, SULT1A4, SULT1B1, SULT1C2, SULT1C3, SULT1C4, SULT1D1P, SULT1E1, SULT2A1, SULT2B1, SULT4A1, or SULT6B1.

[0024] In some examples, the composition contains natural levels or extracts of minoxidil sulfotransferase enzymes, natural levels or extracts of phenol sulfotransferase enzymes, and/or natural levels or extracts sulfotransferase enzymes derived from Populus trichocarpa, Populus x canescens, Salix sp., Arabidopsis thaliana, silver poplar (Populus alba), Simon's poplar (Populus simonii), S. purpurea, P. tremuloides, I. polycarpa, P. nigra, Oryza sativa, Salicaceae family, Poplars (Populus sp.), Idesia polycarpa - Japanese orange cherry, Potato (Solanum tuberosum), Cabbage (Brassica rapa), Populus trichocarpa (Black cottonwood), Salix Sp. (Willow tree), Cotton (Gossypium), Olea europaea L, Brassica napus, Apium graveolens, brassica oleracea, Saccharina japonica, Solanum tuberosum, and/or Black cottonwood. The natural levels or extracts of minoxidil sulfotransferase enzymes, phenol sulfotransferase enzymes, and/or sulfotransferase enzymes is/are present in amounts ranging from 1%-100% by weight.

[0025] In some examples, the sulfotransferase enzyme can include OeST1.

[0026] In some examples, the method can involve quantifying activity of SULT1A1 in dermal papieli cells and/or dermal sheath of the subject.

[0027] In some examples, the method can involve determining a therapy treatment using the composition based on the quantitative measurement of activity of SULT1A1 in dermal papieli cells and/or dermal sheath of the subject.

[0028] An example can relate to a composition for increasing sulfotransferase enzyme activity in a scalp and/or a liver of a subject suffering from alopecia. The composition can include an alkalizing agent and a sulfotransferase enzyme.

[0028a] In another aspect, the present disclosure refers to a composition for increasing sulfotransferase enzyme activity in a scalp and/or a liver of a subject suffering from alopecia, the composition comprising: an alkalizing agent and a sulfotransferase enzyme.

[0028b] In another aspect, there is provided a use of a composition comprising an alkalizing agent and a sulfotransferase enzyme in the manufacture of a medicament for increasing sulfotransferase enzyme activity in a scalp and/or a liver of a subject suffering from alopecia.

[0029] An example can relate to a method for increasing sulfotransferase enzyme activity in a scalp and/or a liver of a subject suffering from alopecia. The method can involve administering a composition comprising an alkalizing agent and a sulfotransferase enzyme to a subject suffering from alopecia.

[0030] As used herein, the terms "prevent" or "prevention" and other derivatives of the words, when used in reference to alopecia, e.g., androgenetic alopecia, can refer to a reduced likelihood of alopecia in an individual receiving a given treatment relative to that of a similar individual at risk for alopecia but not receiving that treatment. As such, the terms "prevent" and "prevention" can encompass a treatment that results in a lesser degree of alopecia than would be otherwise expected for a given individual. Efficacy for prevention of alopecia can be established through controlled studies, e.g., in which a subject is administered a treatment (e.g., a topical, oral, transdermal, etc.) and another subject is administered a placebo. Under these circumstances, if the subject treated with the treatment undergoes less hair loss over time relative to the subject receiving the placebo, e.g., at least 5% less, at least 10% less, at least 15% less, at least 20% less, at least 25% less, at least 30% less, at least 35% less, at least 40% less, at least 45% less, at least 50% less or beyond, the treatment can be considered effective for the prevention of alopecia.

[0031] As used herein, the term "subject" refers to a human or animal in need of a therapeutic treatment for androgenetic alopecia or any other form of alopecia.

[0032] As used herein, the terms "treat," "treatment," or "treating" refer to therapeutic treatments, wherein the object is to reverse, alleviate, ameliorate, inhibit, slow down or stop the progression or severity of a disease or condition, e.g., androgenetic alopecia or other form of alopecia. The term "treating" can include reducing or alleviating at least one adverse effect or

symptom of the disease or condition. Treatment can be considered to be generally "effective" if one or more symptoms are reduced. Alternatively, treatment can be "effective" if the progression of a disease is reduced or halted. That is, "treatment" can include not just the improvement of symptoms, but also a cessation of, or at least slowing of, progress or worsening of symptoms compared to what would be expected in the absence of treatment. Beneficial or desired clinical results can include, but are not limited to, alleviation of one or more symptom(s),

diminishment of extent of disease, stabilized (e.g., not worsening) state of disease, delay or slowing of disease progression, amelioration or palliation of the disease state, remission (whether partial or total), and/or decreased mortality. For example, treatment can be considered effective if the extent or amount of hair loss is reduced, or the progression of hair loss is slowed or halted. The term "treatment" of a disease can also include providing relief from the symptoms or side-effects of the disease (including palliative treatment).

[0033] Efficacy of treatment to treat or prevent alopecia can be determined by monitoring the density of hairs on a given area of the subject's body, e.g., a given area of the scalp. For example, if the rate of hair loss is reduced, e.g., by 10% or more following treatment, the treatment can be considered effective for the prevention of alopecia. Similarly, if hair density remains the same, the treatment can be considered to be effective for the prevention of alopecia. If the density of hair increases, e.g., by 5% or more, e.g., by 10% or more following treatment, the treatment can also be considered effective for the treatment and/or prevention of androgenetic alopecia. Efficacy of treatment to treat or prevent androgenetic alopecia can be determined by monitoring global photography. For example, the patient or an expert can assess the treatment response utilizing before and after global photographs.

[0034] As used herein the term "alopecia" refers to all forms of hair loss in humans or animals, both male and female, including but not limited to traction alopecia, androgenetic alopecia, male pattern baldness, female pattern hair loss, alopecia areata, alopecia universalis, telogen effluvium, chemotherapy induced alopecia, hair shedding, eyebrow hair loss, beard hair loss, hair thinning, etc. The term permits the presence of elements that do not materially affect the basic and novel or functional characteristic(s) of that example.

[0035] To utilize the compositions described herein, subject can apply an effective amount of the composition to the scalp. The term "effective amount," as used herein, can be an amount which is effective in preventing or treating hair loss.

[0036] Further features, examples, objects, advantages, and possible applications of the present disclosure will become apparent from a study of the examples described below, in combination with the Figures, and the appended claims.

DETAILED DESCRIPTION OF THE INVENTION